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**Insulin Pump Use in Children with Type 1 Diabetes:**

**An Exploration of Families' Experiences.**

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Doctorate in Clinical Psychology

University of Edinburgh

August 2012

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## 1. ABSTRACT

**Introduction:** The management of type 1 diabetes through the use of Continuous Subcutaneous Insulin Infusion (CSII); also known as insulin pump therapy, has become an increasingly popular option for children and adolescents. A systematic review of studies that measured Quality of Life (QoL) in children associated with CSII was conducted. Eighteen studies were reviewed, and the results showed insufficient evidence to conclude that CSII improves QoL in children and adolescents with type 1 diabetes. The current study aimed to address the gap in the literature by exploring children and parents' perspectives on the use of CSII for managing diabetes.

**Method:** Data were gathered from five children aged 8 – 14 years (and five parents), using one to one semi-structured interviews. Interviews were recorded, transcribed and analysed using Interpretative Phenomenological Analysis (IPA).

**Results:** Five super-ordinate themes were identified for parents: *'Parenting a Child with Diabetes'*; *'Worth the Hard Work'*; *'Strive for Normality'*; *The Pump as an Enabler'*; and *'An eye on the Future'*. Three Super-ordinate themes were identified for children *'Feeling Different'*; *Grappling for Control'*; and *'Better...'* which were associated with a central theme of *'Developing a Relationship with the Pump'*. Children's data is presented separately within a journal article format.

**Discussion:** Findings suggest that parents value the insulin pump, despite acknowledging the challenges, particularly the hard work required to manage it. Children seemed to have an ambivalent but developing relationship with the insulin pump. They experience a number of benefits and drawbacks associated with the use of CSII and it seems to affect their identity and their locus of control.

**Conclusion:** This research provides a greater insight into the lived experience of CSII for children and their parents. The benefits of CSII seemed to outweigh the challenges involved particularly for parents; and children seemed to be developing a relationship with the pump within the realms of their relationship with diabetes.

**Title**

**A systematic literature review: Is quality of life in children and adolescents with type 1 diabetes improved with insulin pump use?**

Written in accordance with author guidelines for:  
Pediatric Diabetes

Abbreviated title for running head:  
Pediatric Quality of Life & Insulin Pumps



## **ABSTRACT**

### **Background:**

Advances in technology and recommendations in National guidelines have made insulin pumps an attractive treatment option for children and adolescents with type 1 diabetes. However the evidence in relation to medical and psychosocial outcomes remains mixed.

### **Objective:**

To systematically review and synthesise the published literature addressing whether there are quality of life (QoL) benefits associated with insulin pump in children and adolescents with type 1 diabetes.

### **Methods:**

A systematic search was performed using electronic databases (Medline, Embase, CINAHL, PsycINFO, Web of Knowledge and the Cochrane Library) and published references, to identify relevant published studies up to May 2012. 248 potential relevant articles were identified from examination of titles and abstracts published during the specified time frame. Of these, 38 articles were retrieved in full text, of which 18 fulfilled the specific criteria for inclusion.

### **Results:**

Ten studies were controlled trials (of which six were randomised), and the remaining eight studies were uncontrolled. In terms of overall methodological quality, seven were rated as 'high', nine as 'moderate' and two as 'poor'. The findings indicated that assessment of QoL is highly heterogeneous resulting in mixed results and making it difficult to compare findings.

### **Conclusions:**

To date, there is insufficient evidence to suggest conclusively that CSII improves QoL in children and adolescents with type 1 diabetes. Assessment of QoL is inconsistent, making it difficult to make a clear judgment on the QoL benefits associated with insulin pump use. Implications for clinical practice and future research are highlighted.

**Keywords:** Diabetes Mellitus, Pediatric, Insulin Pump, Continuous Subcutaneous Insulin Infusion, Quality of Life.

The global prevalence of diabetes mellitus was 2.8% in the year 2000 and is estimated to rise to 4.4% by 2030; this equates to 71 million people worldwide with diabetes in 2000 and 366 million in 2030 (1). It is forecast that by 2020 new cases of type 1 diabetes in European children younger than five years will double and the number of cases younger than 15 years will rise by 70% (2). Treating children and adolescents with diabetes is complicated, due to unpredictable activity levels, eating patterns and growth, limited size of injection sites and sleep patterns (3). Glycemic control in children under the age of 15 is poor, with a very small percentage achieving optimal blood glucose control (4), yet good diabetes control in childhood and throughout adolescence can reduce complications in later life (3, 5).

Continuous subcutaneous insulin infusion (CSII), otherwise known as insulin pump therapy, is an intensive therapy that delivers insulin continuously from a refillable storage reservoir by means of a subcutaneously placed cannula (6). This has become an attractive treatment option for children and adolescents with diabetes due to the growth in research advocating it as a gold standard treatment (5) and endorsement from National guidelines (6, 7).

A meta-analysis of 52 studies found that CSII was associated with significant improvements in glycemic control (8). A Cochrane review of 23 randomized controlled trials found a statistically significant difference in Glycated Haemoglobin A1c (HbA1c) favoring CSII and a reduction in severe hypoglycemia in the CSII group (9). It is also suggested that CSII can lead to a decrease in distress associated with hypoglycemia and contribute to an increase in acceptance of diabetes (10, 11). In the pediatric population, a meta-analysis of 6 studies showed that CSII was significantly

more effective than Multiple Daily Injections (MDI) in reducing HbA1c in children, though only one RCT showed a significantly lower HbA1c in the CSII group compared with the MDI group. Furthermore, CSII was associated with relatively low insulin requirements without change in Body Mass Index (BMI) and low rates of Diabetic Ketoacidosis (DKA) and severe hypoglycemic events (12). However a number of additional factors (motive, education and acceptance of the treatment) contribute to the success of insulin therapy (13), which are not always measured or controlled in studies. There is limited evidence in relation to mortality, morbidity and costs (9).

Although metabolic control and other medical outcomes (e.g. hypoglycemia, DKA), are essential in the assessment of diabetes treatment, Quality of Life (QoL) should not be overlooked. The World Health Organisation (WHO) defines QoL as an individual's perception of their position in life, in the context of culture and value systems and in relation to goals, expectations, standards and concerns (14). There are instruments for measuring diabetes-related QoL in children and adolescents, however some researchers have argued that the notion of disease specific QoL is unhelpful, as life cannot be separated into what is influenced by a health condition and what is influenced by all other experiences (15). It seems that no clear consensus has been reached, given that both generic and diabetes specific measures are used in research.

Despite inconsistency in measurement, the importance of measuring QoL is recognized. Diabetes in general has been shown to impact negatively on QoL (16), and age related differences have been found, particularly within the under 18 group

(17). It is suggested that insulin pumps bring QoL benefits, such as flexibility, autonomy, and improved sleep and socialization (6).

A limited number of systematic reviews have examined the effects of the insulin pump; most exclusively with adults. The few that have been conducted with a pediatric population have been qualitative (18); only looked at children under 6 years (19); did not include QoL (13); or reviewed all outcomes of CSII (12, 20, 21). One review that focused exclusively on QoL included both adults and children (22), and only included studies up to 2005. This systematic review aimed to evaluate and summarise the current published evidence for the effects of the insulin pump on quality of life of children and adolescents aged 0 – 18 years, and to make recommendations for future research and clinical practice based on the findings.

## **METHOD**

### **Search strategy**

A systematic literature search was carried out in accordance with guidance produced by the Centre for Reviews and Dissemination (23). Studies were identified using Psycinfo, Medline and Embase Review databases, Cochrane Library, CINAHL, Web of Knowledge and Google Scholar. The search was conducted using the following keywords including the Boolean operators 'AND' and 'OR': "Diabetes" OR "Diabetes Mellitus" AND "insulin pump" OR "insulin infusion system" OR "continuous subcutaneous insulin infusion" AND "quality of life". Database searches were limited to years 2001-2012, English Language and age 0 – 18 years. All duplicates were removed. Additional studies were located from hand searching key journals (Journal of Pediatric Psychology, Diabetic Medicine & Pediatric Diabetes). Finally, the reference sections of the most recent review articles were examined to ensure that no studies had been missed (8, 12, 13, 19-22).

### **Inclusion/Exclusion Criteria**

For each paper identified from the database searches, titles and abstracts were screened against inclusion criteria (See Table 1). No restrictions were made regarding group size or specific age groups (within the limits) in order to maximize the number of eligible studies.

### **Data Extraction and Quality Rating**

Papers meeting all aspects of the inclusion criteria were evaluated using a quality assessment tool constructed from guidance outlined by the Scottish Intercollegiate

Guidelines Network (SIGN) (24), The Critical Appraisal Skills Programme (CASP) (25).

**Table 2.1 Inclusion Criteria**

<b>Category</b>	<b>Inclusion</b>
<b>Study Population</b>	Children (aged 0 – 18 years) with type 1 diabetes
<b>Type of Study</b>	Randomised Controlled Trials, Non-randomised controlled trials and Pre/Post studies using quantitative methods and analysis
<b>Intervention</b>	Insulin pump, no additional intervention
<b>Publications</b>	Journal articles published between 2001-2012 in English Language
<b>Outcome Measures</b>	Quantitative QoL measure for children, parents or both.

and key papers (26, 27, 28) (Appendix 1). The evaluative criteria included 23 questions covering five main areas: study rationale, participants, design/method, results/statistical analysis and discussion/conclusions, yielding a possible score of 35. Each paper's total score was converted into a percentage to define a quality

rating description of, 'High Quality' (>75%), 'Moderate Quality' (50-74%); or 'Poor Quality' (<50%).

An independent rater used the same quality assessment criteria to independently assess nine randomly selected studies (50%). All of the studies assessed were rated in the same category. Five studies received the same total score, three studies received different scores (two studies differed by one point and one differed by two points). Disagreement between raters was resolved by discussion.

The quality ratings calculated for each study are detailed in Appendix 2

## **RESULTS**

### **Results of Search Strategy**

The search identified 248 articles after duplicates were removed. Of these, 133 papers were excluded on the basis of title and 77 were excluded after reviewing abstracts against the inclusion criteria. Following full application of the inclusion criteria 38 articles were retrieved in full text form and reviewed against inclusion criteria. The final number of studies fully meeting the specified inclusion criteria was 18 (Appendix 3 illustrates the search strategy and pathway).

### **Description of Included Studies**

Characteristics of the studies are shown in Table 2. Five were conducted in Europe, nine in the USA, three in Israel and one in Japan, with a total number of 930 participants aged between 0 and 18 years (sample sizes ranged from 15 to 160). Four studies looked at young children (<6 years), and required parents to complete the QoL measure by proxy. A further four studies looked at both child and parent (by proxy) measures of QoL. QoL measures included the Diabetes Quality of Life-Youth measure (DQOLY) (47), Pediatric Quality of Life Inventory (PedsQL) Diabetes Module 3.0 (48), KIDSCREEN-10 Index and the diabetes-specific module (KINDL-DM) (49) and Insulin Therapy-Related Questionnaire on Quality of Life (ITR-QOL) (50), author-adapted version of Diabetes Quality of Life (DQOL) (51).

### **Methodological quality of included studies**

Seven papers were rated as high, nine as moderate and two as low quality (see Table 2.2). Scores ranged from 43% to 86%. Ten studies were controlled trials, of which six were randomised. The remaining eight studies had no control group.



Study Author, year, context	Design and Quality Rating	Aims	Included parent/ carers	Child Age Range	Sample Size	Length /Timing	No. Completed	Outcomes Assessed	Quality of Life Measures Used	Significant Results/Main Findings
Barczykowska <i>et al.</i> (29) 2011 Poland	Non Randomised Controlled Study  Moderate (54%)	To rate quality of life of children using CSII  To determine if perceived quality of life differs from healthy peers	Yes	8 – 12	Total 98  48 CSII  50 healthy peers	n/a	98	Quality of Life	PedsQL  Diabetes Module 3.0	Children with T1D using CSII perceive a higher QoL than healthy peers  No statistical analysis
Wu <i>et al</i> (30) 2010 USA	Non Randomised Controlled Trial  Moderate (63%)	To examine medical and psychosocial outcomes for adolescents using MDI vs. CSII	Yes	12 – 17	Total 62  26 CSII  36 MDI	n/a	62	HbA1c  Quality of Life  Parenting Stress	DQOLY	No significant QoL differences between CSII and MDI
Hilliard <i>et al.</i> (31) 2009 USA	Pre/Post  High (77%)	To examine family & individual psychosocial, medical & demographic factors associated with QoL after transition to CSII	Yes	8 – 17	Total 53  53 CSII	Total 1 year  (measures at 1, 6 & 12 months)	1 year – 28  (6 mths – 38)  (1 mth – 53)	Quality of Life  Anxiety  Depression  Family Environment	DQOLY	No sig difference on total QoL score pre/post  Sig improvement on satisfaction (p=.03) and impact (p=.04) subscales pre/post
Muller- Godeffroy <i>et al.</i> (32)	Multi centre prospective pre/post study	To investigate psychosocial aspects of CSII in children	Yes	12 - 16	114	6 months	6 mths - 88	Quality of Life  Family	KIDSCREEN 10  KINDL-DM	No sig difference in overall QoL scores  Sig increase in diabetes

2009	High (77%)								Burden	specific QoL (P<0.001)
Germany									Diabetes Specific Family Conflict	
Nuboer <i>et al.</i> (33)	An open-label, randomized, prospective parallel design	To investigate changes in QoL and impact of disease by CSII or MDI	Yes	4 – 16	Total 39 20 CSII 19 MDI	14 months total First 3 months - all MDI  months 3- 7 - 19 MDI 20 CSII months 7- 14 - all CSII	38	Quality of Life	PedsQL	No significant diff btw MDI and CSII during randomization phase
2008								Impact of disease		Significant improvement in PedsQL during months 7-14 for all children
Netherlands	High (83%)							HbA1c		
Johannesen <i>et al.</i> (34)	Prospective Matched Controlled study	To compare CSII and MDI in adolescents	No	13 - 18	Total 56 30 CSII 26 MDI	1 year	Not stated	Quality of Life	Not stated	No significant difference in QoL scores either between groups or within groups over time.
2008	Moderate (60%)							HbA1c		
Denmark								BMI		
								Episodes of hypoglycemia and DKA		
Kawamura <i>et al.</i> (35)	Prospective intervention study	To evaluate medical and psychological aspects of CSII	No	6 – 18	26	4 months	22	Quality of Life	ITR-QOL	No significant improvement pre – post.
2008								HbA1c		
Japan	Moderate (54%)									

Opipari-Arrigan <i>et al.</i> (36)	Randomised Controlled Trial	To compare medical, nutritional and psychosocial outcomes of CSII with MDI	Yes	3 – 5	18	6 months	14	Quality of Life	PedsQL Diabetes Module 3.0	Significant decrease in diabetes related worry domain in CSII group
2007	Moderate (71%)							Parental Anxiety and Depression		
USA								HbA1c		
								Calorie Intake		
Cogen <i>et al.</i> (37)	Pre/post	To explore diabetes related QoL in transition to CSII examining prior regimen	No	9 - 15	52	6 months	6 mths – 38	Quality of Life	DQOLY	Significant improvement in QoL for those children whose prior regimen was conventional
2007	Poor (43%)					measures at 1 mth and 6 mths	(1 mth – 52)			No significant improvement in QoL for those children whose prior regime was basal bolus
USA										
Juliusson <i>et al.</i> (38)	Pre/post	To study the impact of CSII on health related QoL	No	9 - 17	31	15 months	26	Quality of Life	DQOLY	No significant improvement in diabetes related QoL
2006	Moderate (66%)							HbA1c		
Norway								BMI		
								Episodes of hypoglycemia and DKA		
Valenzuela <i>et al.</i> (39)	Non randomized controlled trial	To compare Health related QoL in MDI to CSII	Yes	5 - 17	160	n/a	160	Quality of Life	PedsQL Generic Module 3.0	No significant difference in QoL between CSII and MDI
2006	High (86%)							Adjustment		

USA									PedsQL Diabetes Module	
Fox <i>et al</i> (40)	Randomised Controlled Trial	To assess the effects of insulin pump therapy on diabetes control and family life	Yes	1 - 6	23	6 months	22	Quality of Life	PDQOL	No significant improvement in QoL
2005	High (77%)							HbA1c		Fathers of children in CSII reported significantly more positive changes for themselves
USA								MBG		
								Episodes of hypoglycemia and DKA		
Wilson <i>et al</i> (41)	Randomised Controlled Trial	To compare CSII and MDI in young children	Yes	1 - 6	19	1 year	17	Quality of Life	Modified version of the DQOL	Significant improvement in parental pre/post within CSII group (p=0.03)
2005	High (86%)							HbA1c		
USA								Episodes of hypoglycemia and DKA		No significant difference between groups
O'Neil <i>et al</i> (42)	Descriptive study	To assess the perception of QoL and diabetes knowledge in children with diabetes	Yes	9 - 17	103	n/a	103	Quality of Life	Modified version of DQOL	No significant difference between CSII and MDI
2005	High (77%)							Knowledge		
USA										
Mednick <i>et al.</i> (43)	Pre/Post	To examine satisfaction and QoL following transition to insulin pump	Yes	10 - 18	22	3 – 22 months	22	Quality of Life	DQOLY	Significant correlation between children's pump satisfaction and quality of life.
2004	Moderate (66%)					(Mean = 10.43 mths, SD = 5.05 mths)		Satisfaction		No baseline data
USA										

Shehadeh <i>et al</i> (44) 2004 Israel	Pre/Post  Moderate (51%)	To evaluate the use of CSII as a means of improving QoL and metabolic control	Yes	1 - 6	15	4 months	15	Quality of Life  HbA1c  Pump related side effects	Modified version of the DQOL	Significant improvement in parental QoL pre/post (p<0.01)
Weintrob <i>et al</i> (45) 2003 Israel	Randomised open crossover trial  Moderate (71%)	To compare MDI and CSII	No	8 - 14	23	8 months	23	Quality of Life  Satisfaction  HbA1c  BMI  Adverse Events	DQOLY	No significant difference in QoL between groups
Cohen <i>et al.</i> (46) 2003 Israel	Randomised open crossover trial  Poor (43%)	To compare CSII and MDI in adolescents	No	14-17	16	1 year	12	Quality of Life  Satisfaction  HbA1c  BMI  Adverse Events	DQOLY	No significant difference in QoL overall  Significant improvement in treatment satisfaction section of QoL measure in CSII group

**Table 2.2 Summary of Studies**

Randomisation procedure was clearly described in two of the RCT's and treatment allocation adequately implemented and concealed during the randomization process (33, 41). Seven studies reported their recruitment method in adequate detail for replication (30, 31, 33, 39, 42, 43, 45). Nine studies explicitly reported their inclusion/exclusion criteria (31-36, 39, 41, 45) and twelve provided an adequate justification for the QoL outcome measures used (29, 31-33, 36, 38-44). One RCT explicitly stated that intention-to-treat analysis was conducted (41); only one study reported effect sizes (32).

### **CSII Effect on QoL**

One study measured QoL of children with diabetes using CSII against that of healthy peers (29), reporting a higher perceived QoL (psychosocial domain) in the CSII group; however this study provided no statistical analysis. Nine studies measured QoL of children using CSII against those using MDI; none showed a significant difference between groups (30, 33, 34, 36, 39-42, 45, 46).

Studies indicated some improvement in QoL with CSII. One study (34) initially randomised half the participants to CSII and half to MDI, during which time there were no significant differences between groups. Following the randomization phase all children received CSII, at which point PedsQL scores increased significantly for both groups. Another study showed significant improvement in overall QoL from baseline to completion in the CSII group (41). A further study (37) reported significant increases in QoL for those who transitioned to CSII from a conventional regimen but not for those who transitioned from MDI. In another, diabetes specific

QoL significantly increased in all children, with medium effect sizes reported in adolescents and large effect sizes in school-aged and younger children (32).

Some studies indicated significant improvements in selected aspects of QoL following transition to CSII. A significant reduction in diabetes related worry and satisfaction was found for the CSII group in one study, though other DQOLY scores were unchanged (36). Another (31) found significant improvements in 'satisfaction' and 'impact' aspects of children's QoL following transition to CSII but no significant difference in overall QoL. Another study (44) reported significant improvements in 'impact' and 'worry' sections of the DQOL (parents) following children's transition to CSII.

One study found a significant positive correlation between children's satisfaction with CSII and their QoL, although reported no baseline data for pre/post comparisons (43). Health related QoL was significantly correlated with psychosocial adjustment (parental and child), but not significantly correlated with demographic or disease indicators (39).

## **DISCUSSION**

No studies showed that QoL is significantly better in those children and adolescents with CSII compared to those with MDI. However four studies did show improvements in QoL following transition to CSII and no studies reported reduced QoL or detrimental effects of CSII. Unfortunately QoL tended to be a secondary outcome and very little research has been conducted with QoL as a primary outcome in association with CSII.

Most of the trials lacked important elements that ordinarily ensure a rigorous RCT design, such as double blinding (researchers and participants), though it would have been clearly unfeasible to blind participants. While observational studies lack the control of trials, NICE (6) suggested that children enrolled in observational studies may more closely resemble the population that would be considered as suitable candidates for CSII which increases the validity of the research. Nevertheless, heterogeneity of studies makes it difficult to ascertain the effects of confounding variables such as socioeconomic status, co-morbid conditions, education/knowledge about treatment, contact time and family factors. All studies had methodological shortcomings in some capacity; however only two were rated as poor quality.

It has been suggested that decreasing the rate of severe hypoglycemia can improve QoL (6), suggesting a correlation between diabetes control and QoL. One study found that improvements in glycemic control alone were unlikely to automatically improve QoL (39) and another showed that benefits in QoL were in relation to flexibility, leisure activity and diet, as opposed to glycemic control (43).



The studies in this review used a variety of QoL measures, which individually assess a number of domains. Reported validity and reliability of the measures used across the literature is varied, but generally good. Problems with measuring QoL stem from historical debate over the definition of QoL, the use of different conceptual models to consider QoL,(52), their differing structure and content, the ways they were developed and whether they use a system of weighting (53); limitations which compromise utility and precision. The difficulty in reaching a consensus on the definition of QoL suggests perhaps that it should be considered as an individual construct and should be measured in a patient-centered way (53). Although, measurement difficulties such as comparison of groups, or changes across time would be evident (53).

### **Limitations of Review**

The inclusion criteria for this review were broad, given the relative lack of research in this area, and therefore studies varied in design. This meant that to assess quality, a criteria checklist had to be adapted. Although the checklist was based on guidelines and literature, there may be a greater reliability and validity if a standard measure could have been used. Furthermore, inter-rater reliability was only based on half of the included studies, although the agreement was strong. Given that the studies were conducted globally, it may be that selection procedures for children and adolescents for CSII differ between countries. The review only included articles published in English, which may have narrowed cultural differences, but also excluded relevant studies. The age range was guided by the existing literature and the typical age range in pediatrics; however developmentally children and adolescents may reach

different stages at different ages and studies which covered a larger pediatric population (<21 years) were excluded. The review used a narrative approach to synthesise the evidence, rather than meta-analysis. The findings were felt to be too heterogeneous for such an approach to have any practical meaning.

### **Implications for Future Research and Clinical Practice**

It has been suggested that a large-scale multi-site patient preference study should be conducted to identify the exact QoL effects of CSII on individuals (22). Future research should also be of sufficient duration to consider the longer-term effects (19). The lack of qualitative research in this area means that individual benefits or problems with CSII may have been missed. Conversely, a recent systematic review of the qualitative literature highlighted that the qualitative research to date lacked important quantitative elements associated with CSII e.g. HbA1c. A mixed methods design may address these issues. Ongoing advances in the technology that drives CSII means that research will need to adapt to the changes in this area.

### **Conclusion**

There is no clear evidence that QoL is improved relative to MDI, but that does not mean that CSII offers no QoL benefits for this population and may be in part a function of measurement difficulties. It is recommended that more research be conducted; in particular longer term large scale randomised controlled trials, and qualitative research, which explores the idiosyncratic experiences of CSII for the pediatric diabetic population.

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### **3.1 ABSTRACT**

#### **Introduction**

The management of type 1 diabetes through the use of Continuous Subcutaneous Insulin Infusion (CSII); also known as insulin pump therapy, has become an increasingly popular option for children and adolescents. Lack of research and measurement difficulties make it difficult to form a clear judgment on the QoL benefits associated with insulin pump use. The current study aimed to address the gap in the literature by exploring children and parents' perspectives on the use of CSII for managing diabetes.

#### **Method**

Data were gathered from five children aged 8 – 14 years (and five parents), using one to one semi-structured interviews. Interviews were recorded, transcribed and analysed using Interpretative Phenomenological Analysis (IPA).

#### **Results**

Five super-ordinate themes were identified for parents: *'Parenting a Child with Diabetes'*; *'Worth the Hard Work'*; *'Strive for Normality'*; *The Pump as an Enabler'*; and *'An eye on the Future'*. Three Super-ordinate themes were identified for children *'Feeling Different'*; *Grappling for Control'*; and *'Better...'* which were associated with a central theme of *'Developing a Relationship with the Pump'*.

#### **Discussion**

Findings suggest that parents value the insulin pump, despite acknowledging the challenges and particularly the hard work required to manage it. Children seemed to have an ambivalent relationship with the insulin pump. They experience a number of benefits and drawbacks associated with the use of CSII and it seems to affect their identity and their locus of control.

#### **Conclusion**

This research provides a greater insight into the lived experience of CSII for children and their parents. The benefits of CSII seemed to outweigh the challenges involved particularly for parents; and children's relationship with the pump seemed to be developing within the realms of their relationship with diabetes.

## **3.2 INTRODUCTION**

### **3.2.1 Summary of Systematic Review**

The systematic review highlighted a clear need for further research to explore the Quality of Life (QoL) effects associated with Continuous Subcutaneous Insulin Infusion (CSII) for children and adolescents. Advances in technology and recommendations in National guidelines make insulin pumps an attractive treatment option for children and adolescents with type 1 diabetes in the UK, however the evidence in relation to QoL outcomes is mixed. Although the 18 studies that were reviewed provided a range and depth of information regarding the effects of CSII, the findings were limited by methodological weaknesses and few studies measured QoL as a primary outcome. Specifically, assessment of QoL is inconsistent, making it difficult to make a clear judgment on the QoL benefits associated with CSII. The question therefore about whether CSII improves QoL in the pediatric population remains unanswered. Although there is no clear evidence that QoL is improved, that does not necessarily mean that CSII offers no QoL benefits for this population.

Although the review highlighted a number of quantitative areas that required further exploration, it also specifically highlighted the need for qualitative research to be conducted alongside such investigations. Qualitative studies in this area have been limited to date. A qualitative review concluded that there remains a scarcity of data on how children/young people, and their parents, feel about using insulin pumps (Alsaleh *et al*, 2011).

### **3.2.2 Summary of Qualitative Research**

Alsaleh and colleagues found only six qualitative studies (up to 2009) that described the experiences of children (and/or their parents) using an insulin pump (Alsaleh *et*

*al*, 2011). To the author's knowledge, no further studies have been published examining the experiences of this population. Two studies have been conducted examining the experiences of parents only (Sullivan-Bolyai *et al*, 2004; Wilson, 2008); three studies examined the experiences of both children and parents (Barnard *et al*, 2008; Low *et al*, 2005; Maniatis *et al*, 2001); and one study looked only at children's experiences (Olinder *et al*, 2007). None of the published studies conducted to date have used IPA as a method of analysis. Two studies collected data using questionnaires and four using interviews; data were analysed quantitatively looking at frequencies.

Across the qualitative studies to date, the most reported reason for transition to an insulin pump seems to be the pursuit of a flexible lifestyle, and stable well-controlled blood glucose levels (Alsaleh *et al*, 2011); which was also consistently reported thereafter as an advantage of using the pump. Reported disadvantages highlighted were in relation to visibility of the pump and further physical restrictions (Alsaleh *et al*, 2011).

### **3.2.3 Background to the current study**

As an audit exercise, prior to commencing the current empirical study, pre and post (6 and 12 months) CSII HbA1c data were collected for children in Scotland from a selection of NHS health boards by the author. Across Scotland, 212 children were using an insulin pump at the point of data collection (2011). Full HbA1c data was collected from seven health boards; 6 month data was available for 62 children and 12 month data was available for 51 children. The data were statistically analysed to give an indication of the effectiveness of the insulin pump on HbA1c. The mean HbA1c score before the insulin pump was 8.76 (SD 0.95); at 6 months post pump was

8.11 (SD 0.97) and the mean HbA1c at 12 months post pump was 8.04 (SD 0.94). The data were analysed using paired samples t-tests and showed a significant improvement in HbA1c following the use of an insulin pump at both 6 months post pump ( $t = 5.56, p < 0.01$ ) and 12 months ( $t = 5.16, p < 0.01$ ).

Given that the systematic review was unable to conclude improvements in QoL associated with CSII; and a number of studies showed that improving HbA1c did not necessarily translate to improving QoL (Valenzuela *et al* 2006; Mednick *et al*, 2004), then despite the improvement measured in HbA1c, it could not be assumed that there were improvements in QoL for these families. Furthermore validity and reliability measurement issues make measuring QoL quantitatively difficult. Therefore there seemed to be a strong case to explore the experiences of these children and their families qualitatively.

### **3.2.4 Study Aims**

The current study aims to address some of the recommendations that have been made in the research that has been conducted to date. There is a dearth of qualitative research in this area investigating how children feel about CSII in the context of their daily lives. Specifically, this study aims to address this gap in the literature by exploring children's perspectives on the use of CSII for managing their diabetes, and that of their parents. This research is not hypothesis driven, and instead it will use an exploratory approach. It is hoped that exploring the experiences of children and their parents will help inform knowledge, guidelines and future research for a wider understanding and implementation of CSII for the management of diabetes in children.

### **3.3 METHODOLOGY**

#### **3.3.1 Design**

The current study was a qualitative investigation using Interpretative Phenomenological Analysis (IPA) (Smith, 2009) to explore the nature of families' experiences of insulin pump use, with semi-structured interviews as the method of data collection. The main aim was to provide a detailed account of families' perceptions of this treatment and its effect on their lives.

##### **3.3.1.1 Qualitative Approaches**

To date, the majority of research examining insulin pump use has been quantitative. Quantitative designs typically aim to answer questions about particular phenomena by isolating, predicting or controlling specific variables (Yardley, 2000). Sometimes, however, researchers can find themselves in the possession of questions that are not easily answered by such designs. Qualitative research can often answer such questions and can be useful when a research area is particularly complex or there is little known about it. However qualitative designs should not be viewed as competing with quantitative research but rather as complementary: they can provide different perspectives and answer different questions about any one phenomenon. Qualitative research has experienced a steady growth, since the 1960s with the *Journal of Qualitative Sociology* first published in 1978 (Holloway & Wheeler, 2009). Qualitative approaches enable researchers to question meanings, examine processes, identify barriers and facilitators to change and uncover reasons behind success or failure of interventions (Starks & Trinidad, 2007) and as such they have much to contribute to research in healthcare; particularly given the governmental shift



towards service-user involvement outlined in various documents: Patient Focus and Public Involvement (Scottish Executive, 2006); Better Health, Better Care: Action Plan (Scottish Government, 2007); NHS Scotland Quality Strategy (Scottish Government, 2010a); and The Diabetes Action Plan (Scottish Government, 2010b).

### 3.3.1.2 Use of Qualitative Approaches with Children

Much of the qualitative research examining illness in young people has been conducted from the parent's perspective and therefore much of our knowledge of illness in young people is based on adult concepts (Woodgate, 2001) Where young people's views have been considered, the approaches have tended to be quantitative. Eiser and Morse (2001) provide a number of reasons why qualitative approaches should be considered over quantitative when researching children. Firstly, children may not have the cognitive skills necessary to respond to a questionnaire where they are required to process a question, retrieve the relevant information from memory and give an answer to fit into a format or category. Secondly, quantitative data collected from children may be more susceptible to response bias. Thirdly, the type of scale and the terminology used within response scales and questionnaires can be interpreted differently by individuals and can influence a child's response (Eiser & Morse, 2001). So when it comes to children's health, although it is vitally important to seek information about children, it is equally important to seek information from them (Docherty & Sandelowski, 1999). It has been suggested that children with chronic illness develop the ability from an early age to understand and manage a range of elements in their lives (Nicholas *et al.*, 2010). Docherty and Sandelowski (1999) have found that children as young as three years old can recall and give descriptions of experiences related to illness. Children as young as four years old

have been shown to demonstrate an understanding about the principles of managing their diabetes (Alderson *et al.*, 2006). Furthermore, Alderson *et al.* (2006) suggest that research literature needs to include more reports about children's views if it is to realistically reflect clinical practice in the 21<sup>st</sup> century. Qualitative research with children allows us to step outside the boundaries of our adult thinking and discover potential differences between our perceptions and those of the children to whom we speak (Mishna *et al.* 2004).

### 3.3.1.3 Interpretative Phenomenological Analysis (IPA)

Founded by Smith (1996), IPA is an approach to qualitative research, which has its theoretical roots in phenomenology, hermeneutics and idiography (Smith *et al.*, 2009).

Phenomenology can be described both as a philosophy and a research method and has informed a number of methodological approaches (including IPA). Phenomenology is "a philosophical approach to the study of experience" (Smith *et al.*, 2009 p 11); a contribution to a deeper understanding of lived experience (Starks & Trinidad, 2007). Hermeneutics can be described as theory of interpretation (Smith *et al.* 2009). IPA aims to explore the human lived experience expressed in its own terms rather than providing objective explanations according to predefined categories (Smith & Osborn, 2007; Smith *et al.*, 2009). A participant's experience is measured from his or her own perspective whilst recognising the significance of the researcher's interpretation. This two-stage or "double hermeneutic", is the researcher trying to make sense of the participant making sense of what is happening to him (Smith, 2011). Idiography refers to the idea of the particular or the individual (Smith

*et al.* 2009); hence IPA's focus on detail and depth of analysis. This differs from traditional approaches to psychological research where the emphasis is on achieving results that can be generalized. Although idiography does not avoid this notion, it develops generalisations more vigilantly because it establishes them through looking at the particular (Smith *et al.* 2009).

#### 3.3.1.4 Justification of IPA in the current study

Smith *et al.* (2009) suggest that when choosing a qualitative methodology, rather than choosing the best "tool for the job", researchers first need to be clear of exactly what "the job" is. IPA was chosen as the favoured qualitative approach as it fitted with the study's aims, research questions and philosophical position: specifically it's focus on personal meaning and sense-making in a particular context, for individuals who share a particular experience. Whilst IPA was selected as the preferred methodology, this research could have been conducted using a number of qualitative methodologies. Alternative methodologies that were considered were Discourse Analysis and Grounded Theory.

Grounded Theory, which was originally developed by Glaser and Strauss (1967), is the longest standing of the identified qualitative methods, which is an advantage as it holds a degree of credibility and is well known and used in psychological research. Grounded Theory proposes that we should avoid generalising existing theories about how people behave etc. into qualitative research and suggests instead that theory should be based on people's actual experiences (or their accounts of such). Grounded theory is well suited to address sociological research questions, as it focuses on social processes and construction of theories to account for phenomena

(Willig, 2001). Essentially the role of this approach is to generate a substantive theory, that makes sense in its own context drawing categories together to tell a story that examines a social process (Gordon-Finlayson, 2010). The researcher should begin without any preconceived ideas. Ideas will be generated through the process of data collection, constant comparison and analysis, whereas with IPA the researcher comes to the study with their own ideas, understandings, preconceptions and background, as is the case with this study.

Discourse Analysis examines talk and interaction in detail to move beyond understanding the content of data towards understanding its active aim and to explore the construction of reality (Wiggins & Riley, 2010). It allows researchers to question understandings of the world and explore the ways in which they have been positioned and the ways in which discourse can construct subjectivity, self and power (Willig, 2008). Ultimately it aims to explore the cultural and linguistic factors that influence ways of thinking, speaking and acting. This form of analysis can explore how specific discourses have been formed, such as religious or health (Silverman, 2000). Discourse Analysis was considered to be inappropriate for this study due to its focus on discourse practices, specifically the role of language in the construction of social reality (Willig, 2008). Discourse Analysis is very interpretative and may avoid questions of experience, whereas IPA is concerned with gaining a better understanding of the individual experiences; that is, it is interested in the nature or essence of phenomena (Willig, 2001).

IPA has been used at length within health psychology and so a large body of research has grown in this area (Brocki & Wearden, 2006). Exploration of patient

experiences of health conditions and treatments at both an individual and generalised level are increasingly and successfully adopting the use of IPA (Smith *et al.*, 2009). Conditions such as diabetes occur, change and progress over periods of time and IPA is a methodology, which allows for experiences over time to be encapsulated (Brocki & Wearden, 2006). Therefore IPA was considered the most appropriate method for this study.

### **3.3.2 Ethical Considerations**

#### **3.3.2.1 Ethical Approval**

This study was carried out in accordance with the British Psychological Society's (BPS) Code of Ethics and Conduct (BPS, 2009). In addition to the standard ethical considerations given to conducting this research, the researcher also consulted the National Children's Bureau (NCB) Guidelines for Research with Children and Young People (NCB, 2011). An initial research proposal for this study was reviewed and approved by the University of Edinburgh DClinPsychol Ethics committee in the first instance. Thereafter full ethical approval was obtained from the West of Scotland Research Ethics Committee (Appendix 4) and research and development management approval from NHS Forth Valley (Appendix 5).

The main ethical issues arising from the study, along with steps taken to address them are outlined below.

#### **3.3.2.2 Informed Consent**

Fundamental to participation in any research is the need for informed consent. Three

aspects central to informed consent are information giving, voluntary participation and competency (Kirk, 2007), all of which require considerable attention in research with children and young people.

#### *3.3.2.2.1 Information Giving*

Valid consent is underpinned by adequate information and it is important to develop appropriately tailored information for children, and to consider the differences in developmental and chronological ages. For this reason three versions of the Participant Information Sheet (PIS) were developed: one for parents and two for children (younger and older) (Appendix 6-8). The PIS explained why the study was being carried out, what it would involve, issues relating to confidentiality and how to find out more information. It can be particularly difficult to convey the meaning of the research to children, in particular that their participation will be of no direct benefit to them (Kirk, 2007). Considerable effort was made to ensure that the PIS and the consent sheets were accessible for children. CHANGE, a national organization led by people with disabilities, developed guidelines for producing accessible and easy to read documents, which were consulted in this process (CHANGE, 2010). Participants received the PIS in advance and were contacted at a later stage (of at least 24 hours) to ensure adequate time had been given to read the information, consider options and make a free choice. Children received a separate PIS, which contained the same information written in a developmentally appropriate way, including pictures. The researcher clarified that the family had received sufficient information about the nature of the research to enable them to provide informed consent.

#### *3.3.2.2.2 Voluntary Participation*

Mishna *et al.* (2004) suggest that children are more likely to struggle to use their right to withdraw from a study. Children and parents were made aware that they did not have to consent to taking part and that they could leave the study at any time without any effect on their NHS care. The researcher had to ensure that the parent or responsible adult giving consent was recorded (by name, relationship or role) on the parent study consent sheet (Appendix 9). Children should be encouraged from an early age to sign a consent form, to show that they agree with what is being proposed (Department of Health, 2001). In all cases, the researcher had to ensure that the child had an opportunity to decline to take part, even though a parent or a responsible adult had given consent on their behalf. Children signed a study assent form for this purpose (Appendix 10). This point of voluntary participation was included in the PIS, but thereafter stressed verbally by the researcher before the interviews commenced. Children may communicate their discomfort or desire to withdraw from the research in indirect ways and the researcher needed to be aware of subtle cues from the children (Mishna *et al.*, 2004). The researcher was also mindful that even when children have capacity to understand specific concepts, they lack life experience and therefore may lack the confidence to assert their rights in the research process e.g. their right to withdrawal (Duncan *et al.*, 2009).

#### *3.3.2.2.3 Competency*

Competence is not necessarily measured by chronological age, but rather by developmental stage. The issue of competency means that children must understand what the research is about but also that they must understand the consent process; both of which depend on the child's cognitive abilities (Broome, 1999). Broome

(1999) suggests that this understanding is affected by the child's age and developmental stage, the information they are provided with, and the opportunity they are given to ask questions. It is generally agreed that children between the ages of seven and twelve have reached the stage of 'concrete operations' (Piaget, 1930). This means that they can understand and produce information relevant to their own experiences. The researcher was aware that age-stage theories and methods may over- or underestimate many children's abilities (Alderson *et al.*, 2006), and a minimum age of eight was chosen to account for this. Once children reach the age of 16, they are presumed in law to be competent to give consent for themselves for their own treatment (Department of Health, 2001).

### 3.3.2.3 Risk to Participants

#### *3.3.2.3.1 Vulnerability of the Participant Sample*

It makes sense that the younger a research participant, the less life experience they will have, including experience in engaging in lengthy conversations and discussing their personal experiences (Duncan *et al.*, 2009). As is the case in most research studies, participation risks potential distress for children and/or adults taking part. Children may experience a variety of perceived pressures from taking part in research such as fear of failure, guilt or embarrassment (Davis, 1998). In particular Morse (2007) points out that in qualitative research, the fact that researchers gain access to "intimate information", can render participants vulnerable and disempowered. It was important therefore that the researcher be prepared to contend with any potential anxiety or distress that children may experience as a result of participating in the study (Kirk, 2007). Participants were made aware that



issues could arise which might be upsetting, should they decide to discuss difficult personal experiences relating to their condition. They were advised that they could take a break during or discontinue the interview if they wished. Time was allocated at the end of the interviews to debrief the participants and investigate any concerns following the interview.

MacDonald and Greggans (2008) highlight that it is important not to immediately conceptualise children as 'vulnerable'. They suggest that children's levels of ability to competently participate in and engage with research should not be underestimated if researchers hope to fully understand children's experiences.

#### *3.3.2.3.2 The Research Relationship*

The relationship that develops with participants during the research process requires consideration, specifically when the research is with a potentially vulnerable group such as children. Richards and Schwartz (2002) suggest that there is an inevitable power imbalance in any research relationship, which may be exaggerated when the researcher is a health professional. Duncan *et al.* (2009) suggest that these power issues are magnified with children and young people, given the typical unequal power relations between adults and children in society. Before the interviews began, the researcher explicitly described and discussed her role, specifically that her contact with the family would be short-term, for the duration of the interviews only. It was also emphasised that although the researcher worked in the diabetes service, the research was separate from their usual care from the diabetes service.

#### 3.3.2.4 Confidentiality

The importance of confidentiality within a research setting is unquestionable. Duncan *et al.* (2009) suggest that the validity of research data can be jeopardised when children and young people do not respond honestly due to their concerns about confidentiality. They suggest that despite this being a difficult balance, the main recommendation is to clarify the limits in information for both parents and children, and if necessary deal with any issues promptly (Duncan *et al.*, 2009). At the beginning of the interview, participants were again informed of the limits of confidentiality, as had been emphasized on the patient information sheets and consent forms. Specifically, participants were advised that confidentiality was limited if information emerged which caused the researcher concern regarding the safety of themselves or others. If a disclosure of sensitive information or risk was made by the child it was intended that the interview would be stopped and that the child's parent and/or GP would be informed. The researcher debriefed the children and families after the interviews, which allowed an opportunity to investigate any concerns following the interviews.

MacDonald and Greggons (2008) emphasise the risk that the environment in which the interviews are being conducted can have to confidentiality. Negotiating space and privacy in the first instance was a potential difficulty and thereafter protecting the interests of the child and parents whilst attempting to maintain the integrity of the research. However this did not turn out to be a problem. In fact four out of the five families had space to conduct the interviews separately and in private. One family was concerned that this might not be possible and instead opted to have their interviews conducted in the clinic.

It was also important to consider the protection of participant anonymity, given that they were recruited from a distinct population. Participants were issued with study numbers in place of personal identifiers at the point of data collection. These unique reference numbers were used thereafter for analysis and write-up and direct quotes used in the final report were anonymous. However, even after procedures of anonymisation, quotations and speech mannerisms combined with the context of the research may provide enough information to identify participants, by themselves or others (Richards & Schwartz, 2002).

#### 3.3.2.5 Data Storage

All interviews were recorded using a digital voice recorder and thereafter transferred to audio files and stored on an NHS supplied, encrypted memory stick. This memory stick along with consent to contact sheets, consent and assent forms were stored in a locked filing cabinet in NHS property (only accessible by the researcher) for the duration of the study. Identifiable data such as audio recordings have since been erased. Anonymous data such as transcripts and hard copies of data analysis will be retained in a locked filing cabinet at the Clinical Psychology department for a period of 5 years.

#### 3.3.2.6 Emotional Impact on Researcher

Although the researcher had experience of conducting sensitive interviews as part of her clinical practice, qualitative research can be a more “intense” experience, in particular the intimacy and engagement involved in analysis (Morse, 2007). The researcher therefore had regular access to supervision throughout the course of the study. This supervision was made available in anticipation of the potential distress

that the interviews may cause for the researcher herself and to encourage reflection in relation to the content of and process of conducting interviews, as well as the process of transcription and analysis.

### **3.3.3 Participants**

#### **3.3.3.1 Method of Sampling**

The aim of qualitative research is to explore the experiences of a specific or clearly defined group; therefore purposeful sampling is perfectly appropriate. The aim of the current study was to investigate the experiences of children who have an insulin pump, and that of their family. The sample was homogenous on three factors: having type 1 diabetes, method of insulin delivery, and age. Due to the limited number of participants using an insulin pump, other factors were not controlled for such as sex and duration of diabetes. The researcher had no control over which family member was interviewed, as long as it was a parent or guardian.

#### **3.3.3.2 Eligibility Criteria**

As recommended by Smith *et al.* (2009), the participants in this study represented a reasonably homogenous, purposive sample.

##### ***3.3.3.2.1 Inclusion Criteria***

Participants were children aged between 8 and 14. They had to have type 1 diabetes and have been on an insulin pump for at least 12 months. There was no specific inclusion criterion for parents, as long as their child was eligible.

### 3.3.3.2.2 Exclusion Criteria

The study involved an interview, which required a good standard of English. Therefore, participants who required an interpreter were not eligible for the study.

There were 142 children with diabetes in the health board and ten who use an insulin pump. Of these ten, four children would have been excluded from the study based on the exclusion criteria (three due to age and one due to length of time on the pump).

### 3.3.3.3 Sample Size

The goal of qualitative methodologies is not to obtain a statistically representative, randomised or generalised sample, as statistical power does not apply. Instead, qualitative studies aim to achieve “symbolic representation” (Ritchie & Lewis, 2003); a detailed interpretative account of a specific phenomena in a specific context. They tend to be conducted with small samples that do not represent a population but rather a perspective, challenging the customary association between ‘number of participants and value of research’ (Reid *et al.*, 2005). Although there are no definitive rules on sample sizes for IPA projects within the literature, there are a number of recommendations. Turpin *et al.* (1997) state that a sample size of 6 – 8 participants is appropriate for clinical and health postgraduate programmes. Smith (2009) suggests that numbers of 4 – 10 interviews for professional doctorate studies is sufficient. Purposive sampling was used to recruit a homogenous sample for which the questions would be more significant. The current study aimed to recruit up to 10 participants (i.e. 5 dyads).

### **3.3.4 Research Context**

Given that qualitative research can be considered the consequence of an interaction between participants and researcher, it is recommended that the context in which the research is conducted should be provided to limit potential biases (Yardley, 2000). This section will discuss the research context in terms of characteristics of the service, the researcher and the participants.

#### **3.3.4.1 Characteristics of the Service**

The research took place within an NHS paediatric diabetes service. The service sits within the wider paediatric service which is a multi-disciplinary team including paediatricians, community paediatric nurses, dietitians, podiatrists and clinical psychologists. Although any member of the paediatric service can see children with diabetes, there are two paediatricians and two paediatric diabetes specialist nurses (DSN) who work specifically with this population. Access to dietetics, podiatry and clinical psychology is as required.

The service covers a wide geographical area and accounts for all children with diabetes aged 0-16 years in the health board. Children with diabetes have regular direct access to the paediatric DSN's as required, either through telephone consultation or clinic appointments. Contact with the paediatrician tends to be at outpatient clinic appointments. Children with diabetes who use an insulin pump attend a specific pump clinic with the paediatrician, often accompanied by the paediatric DSN.

#### **3.3.4.2 Characteristics of the Researcher**

The researcher trained over five years: half time as a trainee clinical psychologist and half time as a specialist psychological practitioner in a specialist area. As a trainee clinical psychologist the researcher received training and experience covering models of psychopathology, clinical psychometrics and neuropsychology, lifespan developmental psychology and completed Placements in Adult Mental Health, Learning Disability, Child and Family, Older Adult, Diabetes and Paediatrics. As a Specialist Psychological Practitioner the researcher worked within the adult diabetes service. The child and family and paediatric placements coupled with the researcher's four years experience of working with adults with diabetes influenced the choice of research area. Furthermore, the researcher attended a bi-monthly 'Psychologists in Diabetes' meeting, where she liaised with psychologists from other health boards within NHS Scotland and heard about the experiences of psychologists working in adult and child diabetes services across Scotland.

#### 3.3.4.3 Characteristics of the Participants

**Table 3.1a Child Characteristics**

<b>Participant</b>	<b>Age</b>	<b>Gender</b>	<b>Duration of Diabetes</b>
1	12	Female	11 years 3 months
2	12	Female	2 years 10 months
3	8	Male	6 years 2 months
4	11	Female	1 year 10 months
5	10	Male	2 years 5 months

**Table 3.1b Parent Characteristics**

<b>Participant</b>	<b>Relation to child</b>	<b>Occupation</b>	<b>Number of children in family</b>
1	Mother	Teacher	3
2	Mother	Nurse	3
3	Mother	Housewife	2
4	Father	GP	3
5	Mother	Unknown	1

Ten participants were interviewed in the current study, Five children each with one parent/guardian. Child characteristics are presented in Table 2.1.

### **3.3.5 Procedure**

#### **3.3.5.1 Recruitment**

Recruitment began in March 2012. However the researcher had liaised with the paediatric team prior to this on several occasions. During these meetings, the paediatrician agreed to be the initial point of contact with families. Families with children on insulin pumps attend routine pump clinics with the paediatrician and diabetes specialist nurse. The researcher could not approach participants unless they had agreed with the paediatrician for her to do so. The paediatrician informed the researcher when insulin pump clinics were running, in order for the researcher to make herself available to attend the hospital where they were held. During the families' consultation meetings the paediatrician informed those families that met inclusion criteria about the research study. If the family agreed to meet the



researcher they were introduced following their consultation. The first five families that were approached by the paediatrician, agreed to meet with the researcher, and consequently all five agreed to take part in the study.

Thereafter the paediatrician was available as a link person between the researcher and the family if necessary.

Once potential participants had agreed to meet the researcher, recruitment commenced in three stages:

#### *Stage 1 – Initial contact*

If the family agreed to meet the researcher, they did so following their consultation. This meeting allowed the family the opportunity to meet the researcher in person. The researcher provided the family with the PIS at this point and verbally provided them with an overview of the study. The researcher completed a 'consent to contact' sheet (Appendix 11) with the family, which allowed them to specify preferred contact details and a date for the researcher to contact them to discuss their participation.

#### *Stage 2 – Telephone Contact*

The participants were given as long as they required to read over the information sheets and to consider their participation. The researcher telephoned the participants at the time they had agreed. During the arranged contact, participants had the opportunity to ask any questions that they had and discuss any concerns. They indicated whether they would like to proceed with the study and if so make

arrangements for the researcher to visit their home.

If potential participants indicated that they did not want to take part in the study, they were thanked for their initial interest and their details were destroyed.

### *Stage 3 – Gaining Informed Consent and Interview.*

If the participants indicated that they wanted to take part then a meeting was arranged. The meeting was carried out at the family's home to ensure the least disruption for the family, unless they indicated that they would prefer to meet in a clinic. If the family chose to meet at a clinic then there was a chance that they would need to meet on two occasions (one for the child interview and one for the parents interview), unless there were two parents/guardians available to attend and one could supervise the child while the parent was being interviewed. If the participants were happy to give informed consent at this first meeting, then this would take place and the interviews could commence thereafter. However, if the participants decided that they would like some more time to contemplate participation then the researcher arranged to visit again at a later stage. Participants were free at that point (or any other point) to withdraw from the study if they wished.

Following the gaining of consent/ assent, the interviews took place.

### 3.3.5.2 Interviews

#### *3.3.5.2.1 Interview Schedule*

The researcher compiled an initial interview schedule (Appendix 12), which she

reviewed with her clinical supervisor (who had experience of qualitative research methods). The clinical supervisor suggested some minor changes to the original schedule to avoid the use of questions that could be potentially leading. An NHS Medical Research Ethics Committee also reviewed the interview schedule.

The development of the interview schedule was influenced by the guidance provided in the qualitative literature (Smith *et al.*, 2009; Willig, 2001) and from consulting the relevant research literature on interviewing children (Docherty & Sandelowski, 1999; Instone, 2002; Kortessluoma *et al.* 2003; Punch, 2002). The interview schedule consisted of a number of open-ended neutral questions. The specific topic areas that were covered within the interview were based on relevant literature (Alsaleh, *et al.* 2012) and designed to follow a temporal sequence to explore the experience of CSII in its entirety. Due to the possibility that some questions would be insufficient to elicit satisfactory responses, a number of probes were developed for each question. Questions were developed in such a way that they could not be answered with only a negative or a positive answer.

The interview schedule was as similar as possible for the parents and children and certainly covered the same topics:

- Diabetes before the insulin pump
- First hearing about the insulin pump
- Getting started on the insulin pump
- Learning to first use the insulin pump
- Managing the insulin pump
- The effects of the insulin pump on the child's life

- The effects of the insulin pump on family's lives

#### *3.3.5.2.2 Pilot Interview*

Pilot interviews have been shown to add to the reliability and validity of the actual interviews (Kortessluoma *et al.*, 2003). In order to test the feasibility of the interview schedule, two pilot interviews were carried out with one family. Following these interviews the researcher sought feedback from the parent and the child about the questions asked and about the interview process in general. A clinical supervisor also examined the transcripts of these pilot interviews. The feedback from both sources did not indicate that the interview schedule needed to be revised. Pilot interview data were included in the analysis and subsequent results.

#### *3.3.5.2.3 Interview Format*

Semi-structured interviews were conducted on an individual basis. Semi-structured interviews allow the researcher to facilitate a comfortable environment and ask questions that are open and expansive, to create flexibility and enable participants the opportunity to provide a detailed account of their experiences (Smith *et al.*, 2009). Families were offered the choice of locations for the interviews to be held. Interviews were conducted in the family home, unless the family specifically requested a clinic appointment. Interviews at home may be less formal and can allow the child to feel an element of control over the interview environment (Greene & Hogan, 2005). Smith *et al.* (2009) indicate preference for carrying out the interview in a familiar environment such as the participants' own home to help make participants feel more comfortable. However, for some, the home environment may not be appropriate to conduct interviews in, due to interruptions or lack of space. Interviews were

conducted in private. During the child interview, a parent or guardian needed to remain on the premises, though not in the same room, throughout the course of the interview. If the interviews were in the family home then the parent or guardian was in another room in the house. If the interviews were held in the clinic, the parent or guardian waited in the waiting room.

Prior to the interviews beginning, participants were reminded about the limits of confidentiality. They were also reminded about their rights to stop the interview at any point, either for a break or to withdraw from the study. It is important for children to feel like active participants in the research process (Kirk, 2007). The researcher provided children with some potential prompts to indicate that they wished to stop the interview if they were unsure how to verbalise this e.g. hand signals, red card. The researcher also took some time to specifically clarify to the children the role that they would be expected to play, and to re-iterate the purpose of the interview (Docherty & Sandelowski, 1999). Before and during the interview it was important to continue to assure children that there were no right or wrong answers (Kortessluoma *et al.*, 2003).

Prior to and whilst conducting the interviews with the children, the researcher had to consider a number of issues, including the children's blood sugar levels and mealtimes. Children were required to conduct a blood sugar test prior to commencing the interview, to ensure that they were not at risk of experiencing an episode of hypoglycemia. If the child's blood glucose levels were low enough to risk this, the interview would be postponed until their blood glucose levels had increased to a safe level. Interviews could not be conducted if the child was experiencing

extremely low or high blood glucose levels; mainly due to the risk to the child's health, but more specifically extreme blood glucose levels may affect their attention and concentration (Gonder-Frederick *et al*, 2009). The researcher also had to be mindful that interviews were not conducted over mealtimes, as this might increase the risk of extraordinary blood glucose variations due to missing meals.

It was important to use the interview schedule flexibly throughout the interview process to allow the issues raised by participants to be explored. This required active listening skills on the part of the interviewer, and capacity to allow the interview to move away from the schedule at times and to spontaneously probe the participants to find out more about significant things that they had said. The researcher had over four years experience as a Trainee Clinical Psychologist, and therefore extensive experience of the interview process and the listening and reflective skills required to conduct sensitive interviews. The researcher also had experience of working specifically with children and families and could therefore adapt her pace, language and phrasing throughout the interview as appropriate. It has been suggested that children of all ages are likely to withhold emotion-laden information and younger children may withhold information about unpleasant experiences due to fear about eliciting a negative response from the interviewer (Docherty & Sandelowski, 1999). For this reason the researcher had to carefully observe the children's behaviours and non-verbal cues (Instone, 2002). It was important to frequently summarise information throughout the duration of the interviews. This allowed the researcher to check the accuracy of what she had heard, and to allow the participants to feel that they had been heard. At the end of the interview, participants were given the opportunity to comment on the overall

interview experience and ask any questions or raise any concerns.

The duration of the interviews ranged from 22 minutes to 52 minutes 51 seconds, with an average interview length of 34 minutes for children and 45 minutes for parents.

### **3.3.6 Data Analysis**

Interview recordings were transcribed verbatim by the researcher, at which point a code was assigned to each interview and all identifiable information was removed.

The existing IPA literature does not prescribe one method of analysis, but rather a set of common processes for moving from individual accounts to shared themes. It is recommended that the analytic process should be iterative, allowing the researcher to move back and forth through different ways of thinking about the data (Smith, *et al.* 2009). The researcher considered using computer aided software package such as NVivo 9 (QSR International). However, given that the researcher was a relative novice in qualitative methods she decided against it in order to stay as close to the material as possible (Smith *et al.*, 2009). The analytic process conducted in the current study was based on the step-by-step guide developed by Smith *et al.* (2009) recommended for novice qualitative researchers. These steps are summarised below:

#### *Step 1- Reading and re-reading*

Following transcription, the first stage of analysis required that the researcher became immersed in the data through repeated reading of individual transcripts. This idiographic process ensured that the participants were the focus of the analysis.

The researcher noted comments, thoughts and reflections in a reflective diary for later use.

#### *Step 2- Initial noting*

The aim of this step was to produce a complete, detailed set of notes about the data. This included the use of descriptive comments (describing content), linguistic comments (highlighting use of language) and conceptual comments (to provide an interpretation) of the account. These initial comments were noted on a line-by-line basis in the right hand margin of the transcript.

#### *Step 3- Developing emergent themes*

By this stage the data set had grown; consisting of the original transcript and the detailed notes made in stage 2. This larger data set was re-examined as the researcher began to identify developing emergent themes (to capture a pattern of meaning) with a shift to working primarily with the exploratory comments. Smith *et al.* (2009) note that this should reduce the volume of detail whilst maintaining the richness. The themes attempt to capture participant experiences and researcher's reflections in order to develop a more interpretative account (Smith *et al.*, 2009). The researcher noted her own reflections on the data at this stage. Emerging themes were documented in the left hand margin of the transcript, expressed as conceptual phrases or words e.g. relationship with the pump. An example of a coded transcript can be seen in Appendix 13.

#### *Step 4- Connections across emergent themes*

Working with a now established set of themes, the researcher explored patterns and



connections between them to produce higher order themes. Connections were identified and examined through the use of processes such as abstraction, subsumption, polarization, contextualization and numeration (Smith *et al*, 2009). A summary table of super-ordinate themes and sub-themes was produced for each transcript (Appendix 14).

*Step 5- Moving on the next case*

Steps 1 to 4 were repeated for each transcript. In line with IPA's idiographic principles, it was important to allow new themes to emerge with each new case.

*Step 6- Looking for patterns across cases*

The final stage involved searching for patterns and connections across cases. Summary tables for each transcript were compared to identify shared themes, and more isolated themes. It was important at this stage to measure recurrence across cases. For the purpose of this study, themes were considered recurrent if they were present in three out of the five participants' interviews in each group.

The children's transcripts were considered collectively as were the parents. The steps above were therefore conducted for two separate data sets; first the children and then the parents. The researcher considered the optimal way to analyse the data sets, and decided to analyse them separately in line with recent pieces of research looking separately at parent and child data (Griffiths, 2009; Wilkinson, 2010). IPA has been used to gain multi-perspective accounts as shown in a number of studies with directly related groups (Rostill, *et al*. 2011); families (Penny, *et al*. 2009; Dancyger, *et al*. 2010); indirectly related groups, (Larkin & Griffiths, 2004); dyads

written as pairs, (Wane, *et al.* 2009; Clare, 2002; de Visser & McDonald 2007); and dyads written as groups, (Larkin, *et al.*, 2009).

### **3.3.7 Ensuring Quality**

Quality assurance is an important issue, regardless of the methodology. Whereas quantitative methodologies assess the quality and value of a study using methods such as randomised sampling, generalisability and objectivity (Yardley, 2000), the same methods are inappropriate for qualitative methodologies. Yet the quality of qualitative methodologies still needs to be assessed. There is a welcomed, developing body of evidence, growing alongside the expansion in qualitative research, advising on procedures and practices that make good quality qualitative research (Bowen, 2010; Gomez, 2009; Mays & Pope, 2000; Tracy, 2010; Yardley, 2000). There have also been guidelines produced by the Critical Appraisal Skills Programme (CASP, 2006), who work with local, national and international organizations to promote and develop evidence-based approaches in health and social care. Smith *et al.* (2009) specifically cite the work of Yardley (2000) as a basis for checking quality, however these guidelines are applicable to general qualitative research and not specific to any particular method of analysis. More recently, in an attempt to address this, Smith (2011) developed a specific criteria for evaluating the quality of IPA studies.

A series of processes based largely on the Yardley (2000) guidelines, whilst considering the recent evaluation guide by Smith (2011), were used in order to check the quality and validity of this analysis. These principles and the steps undertaken to adhere to them, are detailed:

### 3.3.7.1 Sensitivity to Context

Sensitivity to context is a principle that encompasses a number of facets: the empirical context, the socio-cultural context and the ethical context, which considers the context of the researcher, the participants and their relationship. Smith *et al.* (2009) suggests that directing an IPA study through reference to relevant literature can demonstrate sensitivity to context. Knowledge of the research context in terms of previous research and relevant literature has been covered in previous sections; although a fairly under researched area to date, the researcher ensured sensitivity to the empirical context. Although previous research and theory can and should influence the researcher's interpretation, Yardley (2000) makes particular reference to the fact that the analysis needs to be sensitive to the data itself. It has been suggested that this can be achieved by ensuring that unexpected findings, which may conflict with the researcher's understanding of the area are actively examined.

The social context of the relationship between the researcher and the participants is very important. Smith *et al.* (2009) highlight the potential for power imbalances within this relationship. Participants were aware that the research was being carried out as part of a clinical psychology doctoral thesis, which could have contributed towards an imbalance of power, with the researcher being viewed in an expert role and participants therefore feeling that they had to provide the correct or most socially acceptable responses. The researcher reminded the participants at various points that there were no right answers and that it was their thoughts and opinions that mattered. Participants were also reminded that their involvement in the study was separate from and would in no way affect the care and support they were receiving from the diabetes service; they were also reminded that their transcripts

would be anonymous. The researcher was aware that her role as a Trainee Clinical Psychologist working within paediatric psychology and adult mental health contexts, might impact on the participants responses. The participants may not have had contact with a Psychologist in the past and therefore may have had pre-conceived ideas about the researcher's clinical role, or be confused about what a psychologist does. The researcher's role was explained clearly at various points in an attempt to overcome these issues. Furthermore, the researcher had no involvement in the past, current or future care of the participants.

### 3.3.7.2 Commitment and Rigour

The second principle according to Yardley considers the importance of commitment and rigour, the extent to which the level of detailed analysis is sufficient to ensure the validity of the results (Yardley, 2000).

Commitment can be demonstrated in relatively simple ways such as engaging extensively with the methodology, the topic area and the actual accounts of the participants. The researcher demonstrated commitment to the methodology by reading extensively about qualitative methodologies and extensively reading about the methods and principles of IPA, consulting with her clinical supervisor who is experienced in qualitative methodologies; and liaison with colleagues who were also conducting IPA studies. In addition the researcher has had an interest in the client group and topic area throughout her clinical training, having worked with adults and children with diabetes for four years and conducting various comprehensive literature searches in and around this topic area at various points throughout her training. The researcher demonstrated commitment to the data as all interviews were

transcribed personally, allowing her to become fully immersed with the participants' accounts. This was enhanced through listening to the recordings while reading and re-reading the transcripts as part of the analysis.

Sampling, triangulation and respondent feedback were methods employed by the researcher in order to strengthen the rigour of the study. The researcher tried to select a relatively homogenous sample by sampling only children between the ages of 8 and 14 who had used an insulin pump for at least a year. It was also important to try to gain a broad range of perspectives therefore their duration of diabetes and length of time on the pump may have varied. Furthermore, mothers, fathers or legal guardians could participate in the parent interview, and participants were sampled from a variety of family sizes and backgrounds. Multiple perspectives (triangulation) were used to demonstrate the depth and breadth of the analysis by comparing interpretations from multiple perspectives against each other to refine the findings (Barbour, 2001). This was achieved specifically by having two transcripts reviewed by a clinical supervisor who had experience in qualitative research, and in working clinically and conducting research with people with diabetes. This process corroborated identified themes while offering a different perspective when it came to refining them. Furthermore, the researcher demonstrated the depth and breadth of the analysis by repeatedly checking themes against transcripts to ensure that they developed from the data and by the use of direct quotations from participants and a summary table to represent patterns of themes. Respondent feedback and validation was also used in this study. Following completion of the data analysis, four participants were randomly selected and contacted by the researcher (permission had been given at the point of consent). This allowed the researcher the opportunity

to discuss the findings, for participants to provide feedback, and for the researcher to ultimately assess whether the findings did in fact represent the participants' views.

### 3.3.7.3 Transparency and Coherence

The third principle is labeled Transparency and Coherence. Transparency refers to the extent to which the actual procedure of conducting the research is disclosed and clearly documented, meaning that the process could be replicated. Transparency is a basic requirement for acceptable quality according to Smith (2011). Qualitative research methods should be able to demonstrate the pathway from the data to the final report (Smith *et al.*, 2009), which can be difficult given the fact that much of the final report will be influenced by the researcher's own interpretations. Reflexivity is an important aspect of transparency in IPA, and involves the researcher acknowledging and detailing their position in the study. To maintain a reflexive stance, the researcher used a reflective diary (see section 3.6) during the study to detail thoughts and reflections at various stages of the research, particularly following interviews and during the analysis. The researcher has provided a clear description of the sampling, interview format and process of analysis. Summary tables and figures were used to show the emergence of themes and the relationships between them. Furthermore, the researcher has kept an audit trail throughout the study, which includes all relevant documentation including initial ethics applications, annotated transcripts and various drafts of reports.

Coherence refers to the fit between the presentation of findings and the theoretical background and research questions. To account for this, the researcher's clinical supervisor reviewed transcripts with the analysis process and clinical and academic

supervisors reviewed drafts of the write-up of the study to ensure a coherent fit between theory and method (Yardley, 2000). To achieve an 'acceptable' level of quality the analysis should be interesting, coherent and plausible; a well focused, in-depth analysis with a strong interpretation is considered 'good' quality (Smith, 2011).

#### 3.3.7.4 Impact and Importance

The final principle considers the impact and importance of the research, i.e. the contribution of the research findings to theoretical knowledge and how it translates into practice. Yardley (2000) has referred to this as the 'decisive criterion' by which research should be judged. Furthermore, this principle is referenced widely within qualitative quality appraisal checklists (Mays & Pope, 2000; CASP, 2006; Tracy, 2010).

According to Smith (2011), 'good' quality IPA studies engage and enlighten the reader. It is anticipated that this research, which highlights the experiences of families with children who use an insulin pump, may offer new insights to people with diabetes who may have or consider having an insulin pump, and the diabetes teams who continue to support them. This may have implications for future support individually and locally and potentially for wider service development.

Running head: Children's experiences of Insulin Pumps

**Title**

**A qualitative exploration of Insulin Pump Use  
in children with type 1 diabetes:  
“better...but...”**

Lesley A. Allan, Emily Newman, and Vivien Swanson

Word Count (exc. Figures/tables/references): 5071

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## **STATEMENT OF CONTRIBUTION**

### **What is already known on this subject?**

- Advances in medical technology have made insulin pumps an attractive and desirable treatment option for children and adolescents with type 1 diabetes.
- Evidence has shown that there are significant health improvements to be gained from insulin pump use, if used correctly, although evidence in relation to Quality of Life improvements associated with insulin pump use is mixed.
- Explorations of children's perspectives on the use of insulin pump therapy have been limited.

### **What does this study add?**

- This study adds information on children's perceptions of pump use to the small literature base exploring this issue in the UK.
- The findings emphasise the ambivalent relationship that children have with the insulin pump in relation to their identity and their locus of control and participants described a number of advantages and disadvantages of insulin pump use.
- This study highlights the need for more research into how children with diabetes manage ambivalence.

## **ABSTRACT**

### **Objectives:**

The management of type 1 diabetes through the use of Continuous Subcutaneous Insulin Infusion (CSII); also known as insulin pump therapy, has become an increasingly popular option for children and adolescents. Managing diabetes through the use of an insulin pump can have effects on Glycated Haemoglobin A1c (HbA1c) and quality of life (QoL) for the child, their parents and the entire family. This study aimed to explore the lived experiences of children with an insulin pump.

### **Design:**

The study utilized qualitative methodology involving semi-structured interviews.

### **Methods:**

Five children were recruited, aged between eight and fourteen, with type 1 diabetes, controlled through the use of an insulin pump. Interviews were recorded and transcribed. Data were analysed using Interpretative Phenomenological Analysis (IPA) to allow an in-depth exploration of the children's experience of CSII.

### **Results:**

Qualitative analysis highlighted three super-ordinate themes for children, which underpinned their experience of having an insulin pump: (1) 'Feeling Different, (2) 'Better...' and (3) 'Grappling for Control'; all of which related to a central theme of 'Developing a Relationship with the pump'.

### **Conclusions:**

Findings suggest that children have an ambivalent relationship with CSII. They experience a number of benefits associated with the use of CSII while reflecting on the drawbacks. CSII seems to affect their identity and their locus of control both in positive and negative ways.

**Keywords:** Diabetes Mellitus, Pediatric, Insulin Pump, Continuous Subcutaneous Insulin Infusion, Qualitative Research.

**Abstract Word Count: 220**

Diabetes is a common pediatric chronic illness. A number of factors make treating children and adolescents with diabetes complicated, including: unpredictable activity levels, eating patterns and growth; limited size of injection sites; and sleep patterns (Danne, 2007). Research has shown that glycaemic control in children under the age of 15 is poor with a very small percentage achieving optimal blood glucose control (The Scottish Government, 2010). Achieving good diabetes control in childhood and throughout adolescence can reduce complications in later life (DCCT Research Group, 1994; Silverstein *et al*, 2005). Continuous subcutaneous insulin infusion (CSII), otherwise known as insulin pump therapy, is an intensive insulin therapy that has become an attractive treatment option for children and adolescents with diabetes. This is partly due to the growth in research advocating it as a gold standard treatment (DCCT Research Group, 1994) and partly due to endorsement from National guidelines (NICE, 2004, 2008). CSII makes use of an external pump to deliver insulin continuously from a refillable reservoir by means of a subcutaneously placed cannula (NICE, 2008). The National Institute for Clinical Excellence (NICE) recommends CSII for children under 12 with type 1 diabetes mellitus and for children over 12, provided that Multiple Daily Injection (MDI) therapy has failed; and they are committed and competent to use it effectively (NICE, 2004; 2008).

There are a number of benefits associated with CSII use such as improved glycaemic control and reduced experiences of adverse events such as hypoglycemia and diabetic ketoacidosis (DKA). A meta-analysis of 52 studies (which included both adult and pediatric studies) found that CSII was associated with significant improvements in glycaemic control (Weissberg-Benchall *et al*, 2003). A Cochrane review of 23 Randomised Controlled Studies found a statistically significant difference in Glycated Haemoglobin A1c (HbA1c), favoring CSII (Misso *et al*, 2010). It

has also been suggested that CSII can lead to a decrease in distress associated with hypoglycemia and can contribute to an increase in acceptance of diabetes (Bode *et al* 2002; Barnard & Skinner, 2008). In the pediatric population specifically, a meta-analysis of 6 studies showed that CSII was significantly more effective than MDI in reducing HbA1c in children (Pankowska *et al*, 2009). However it should be remembered that a number of additional factors contribute to the success of insulin therapy, such as motivation, education and acceptance of the treatment (Galli-Tsinopoulou, 2011), not always controlled for in these studies. Families, specifically parents, can also have a key role in children's adjustment to diabetes, their level of care, and specific management regimens (Guthrie *et al*, 2003). Diabetes is likely to be a source of stress for children with diabetes and other members of the family and, may cause significant parental anxiety. Parents may have differing ways of coping with these pressures, and despite their worries and concerns, they have been shown to also benefit from improved outcomes (Guthrie *et al*, 2003). Quality of Life (QoL) can be described as a holistic concept, which attempts to describe how well or not, life works at a particular time (Wallander, 2001). The World Health Organisation (WHO) defines QoL as an individuals' perception of their position in life, in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns (WHO, 1995). Diabetes has been shown to impact negatively on QoL (Bradley & Speight, 2002), and age related differences have been found in the under 18 group (Wagner *et al*, 2004). The specific impact of diabetes may depend on children, parents and families' perceptions and knowledge of self-care and self-management, as well as on the individual features and functioning of families as a whole (Guthrie *et al*, 2003). NICE considered the effect of CSII therapy on QoL and suggested that the use of insulin pumps brought QoL

benefits, such as flexibility, autonomy, and improved socialization (NICE, 2008). A number of studies have measured QoL in relation to CSII, however to date, there is insufficient evidence to suggest conclusively that CSII improves QoL in children and adolescents with type 1 diabetes. Assessment of QoL is inconsistent, making it difficult to make a clear judgment on the QoL benefits associated with insulin pump use. A review of qualitative studies exploring the experiences of insulin pump use in children and adolescents, and their parents concluded that there was a distinct lack of research in this area and more research was required (Alsaleh *et al*, 2012). Only one study carried out an in-depth analysis of interviews (Low *et al*, 2005) and the others used questionnaires and structured interviews. They suggested that the participants highlighted the main advantages in terms of improved diabetes control and a positive impact on QoL (Barnard *et al*, 2008; Wilson *et al*, 2008; Olinder *et al*, 2007; Low *et al*, 2005) and the main disadvantages to be associated with visibility and restrictions (Olinder *et al*, 2007; Low *et al*, 2005). They recommended that future studies should consider exploring mechanical dependency, social interaction and children's autonomy in relation to management tasks (Alsaleh *et al*, 2012).

In light of the paucity of research in this area, the inconsistent findings (particularly in relation to QoL) and methodological constraints, further exploration of CSII experience in children with type 1 diabetes is essential. It seems particularly relevant given the recommendations in National guidelines (NICE, 2008) that the actual experiences of the children using the treatment be explored. Using Interpretative Phenomenological Analysis (IPA), the aim of this study was to broaden the evidence base by exploring children's perspectives on the use of CSII for managing their diabetes in the context of their daily lives.

## METHOD

### Study Design

This qualitative investigation used IPA (Smith, 1996; Smith *et al.*, 2009) to explore the nature of families' experiences of insulin pump use. IPA aims to explore the human lived experience expressed in the participant's own terms rather than providing objective explanations according to predefined categories (Smith & Osborn, 2007; Smith *et al.*, 2009). A participant's experience is measured from his or her own perspective whilst recognising the significance of the researcher's interpretation. This two-stage or "double hermeneutic", is the researcher trying to make sense of the participant making sense of what is happening to him (Smith, 2011). IPA as a methodology, has gained popularity in medical and healthcare research, and exploration of patient experiences of health conditions and treatments at both an individual and generalised level are increasingly and successfully adopting the use of IPA (Brocki & Wearden, 2006; Smith *et al.*, 2009).

### Participants

IPA studies tend to be conducted with relatively small samples that are guided by finding a balance between individual in-depth analysis and exploration of a full range of issues across the sample (Smith *et al.*, 2009). In this study participants were recruited from a local pediatric diabetes service, and were identified by the consultant pediatrician. Participants were children aged between 8 and 14 with type 1 diabetes (duration >1 year) who had been on an insulin pump for at least 12 months. The study involved an interview, which required a good standard of English. Therefore, participants who required an interpreter were not eligible for the study. The first five families (who met the inclusion criteria) approached by the

pediatrician agreed to take part in the study. Ten participants were interviewed in the current study, five children each with one parent/guardian. This article, which is part of a wider qualitative study, focuses only on the children's perspectives. Child characteristics are presented in table (Table 3.1).

**Table 3.1 Participant Characteristics**

Participant	Age	Gender	Duration of Diabetes
1	12	Female	11 years 3 months
2	12	Female	2 years 10 months
3	8	Male	6 years 2 months
4	11	Female	1 year 10 months
5	10	Male	2 years 5 months

### **Data collection**

A semi-structured interview was conducted with each participant. All interviews were conducted by the lead author at the participants' homes and were audio recorded. Children conducted a blood test prior to interviews to ensure that they were not at risk of a hypoglycemic episode during the interview. The duration of interviews ranged from 22 minutes to 42 min, with an average duration of 34 minutes. Interviews were based on an interview schedule developed by the lead researcher (see Table 3.2). The interview schedule was designed to follow a temporal sequence to explore the experience of CSII in its entirety. Willig (2001) suggests that the use of interview schedules enable specific questions to be asked, whilst allowing for flexibility. The interviewer schedule was therefore followed in line with views offered by participants, thereby not directing them and permitting them to say what

felt important to them, while at the same time maintaining a basic framework of inquiry. Prompts were employed throughout interviews to clarify questions or encourage engagement. Children of all ages are likely to withhold emotion-laden information and younger children may withhold information about unpleasant experiences due to fear about eliciting a negative response from the interviewer (Docherty & Sandelowski, 1999), therefore the interviewer had to carefully observe the children's behaviours and non-verbal cues and frequently summarise information throughout the duration of the interviews; a reflective diary and field notes were utilised here.

**Table 3.2 Interview Schedule**

- 
- Diabetes before the insulin pump:  
-*What was diabetes like before you got your insulin pump?*
  - First hearing about the insulin pump:  
-*How did you first hear about the insulin pump?*  
-*Who decided to try the insulin pump?*
  - Getting started on the insulin pump:  
-*Do you remember first getting your insulin pump?*  
-*What was that like?*
  - Learning to first use the insulin pump:  
-*Who taught you to use the insulin pump?*  
-*What was it like learning to use it?*
  - Managing the insulin pump:  
-*What is it like using it now?*  
-*Who manages the pump?*
  - The effects of the insulin pump on the child's life:  
-*Tell me about the overall effects that the insulin pump has had on your life?*
- 

### **Data analysis**

The lead author transcribed interview recordings verbatim. The existing IPA literature does not prescribe one method of analysis, but rather a set of common



processes for moving from individual accounts to shared themes. An iterative analytic process is recommended, allowing the researcher to move back and forth through different ways of thinking about the data (Smith, *et al.* 2009). The transcripts were analysed as a six-stage process, in accordance with the principles of IPA, as outlined by Smith *et al.* (2009). A summary of the analysis involved at each stage of the process is outlined in Table 3.3. During analysis the lead author did not attempt to withhold her own previous knowledge or experiences, instead, previous knowledge and experience informed interpretation.

**Table 3.3 Summary of six stage IPA process.**

Stage	Process
1 Reading and re-reading	Researcher becomes actively engaged with data by immersing oneself in the transcripts.
2 Initial noting	Initial notes are made on a line-by-line basis detailing descriptive, linguistic and conceptual comments.
3 Developing emerging themes	Patterns within the notes are explored as the researcher tries to identify emerging themes.
4 Connections across emergent themes	The researcher explores connections between themes in order to move towards higher-level 'sub-ordinate' themes.
5 Moving onto the next case	Repeating Steps 1-4 for each transcript.
6 Looking for patterns across cases	Patterns and connections across cases are explored in order to integrate to produce 'super-ordinate' themes, which represent the whole group.

### **Quality Assurance**

Quality assurance measures (Yardley, 2008) were carefully utilized by the researcher in order to strengthen study rigour. The lead researcher transcribed all interviews and conducted the analysis. A selection of transcripts were reviewed by the third author. A clear audit-trail of analytical decision making, ensured transparency throughout the research process. The path from emerging themes to super-ordinate themes can be traced through the analysis process from interviews to write-up. A reflective diary was kept throughout the entire process by the first author in order to maintain a reflexive stance. This enabled the first author to document reflections about previous knowledge and experiences, which could impact different stages of the research process.

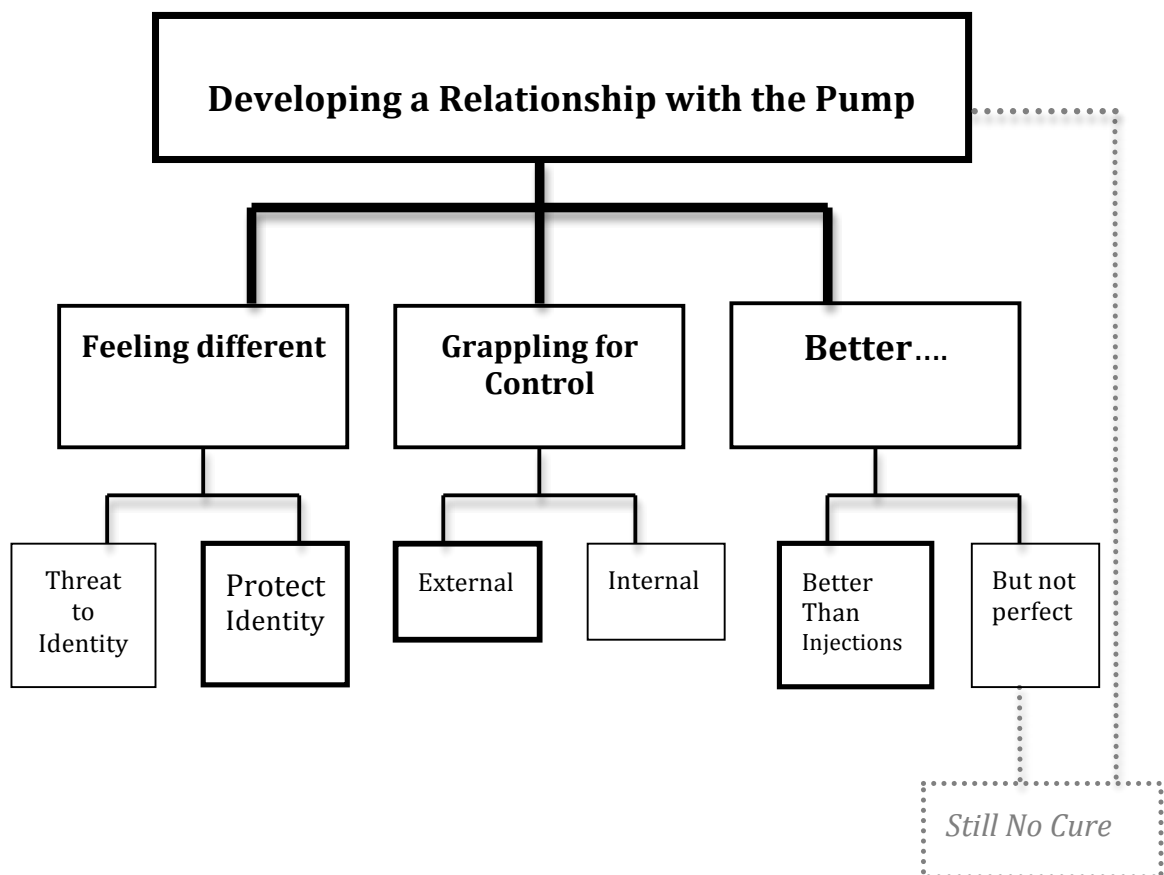
### **Research Ethics**

Participation was voluntary and informed assent was obtained. Identifiable data was made anonymous, and numbers were used for the participants and those they referred to during the interviews. Audio recordings and full, anonymous, transcripts were securely stored. The study research proposal was initially approved by the University of Edinburgh DCLinPsychol ethics committee. Thereafter ethical approval was sought and approved from the local area NHS Medical Research Ethics Committee and NHS Research and Development.

## RESULTS

Analysis of the transcripts produced three super-ordinate themes: 'Feeling Different', 'Grappling for Control' and 'Better...'. The super-ordinate themes were interpreted as being connected by a core theme of 'Developing a Relationship with the Pump'. Figure 3.1 illustrates the relationship between the core theme and the super-ordinate and sub-ordinate themes. Developing a Relationship with the pump is central to the diagram as it was viewed as dominating the children's accounts. When analysing data there can be a connection between themes, which may help the data move to a more theoretical level (Smith *et al*, 2009); hypothesised relationships between the themes are discussed in an attempt to reflect the overall experiences.

**Figure 3.1 Schematic Representation of the relationship between themes**



In addition to the super-ordinate and sub-ordinate themes, an additional 'gem' emerged; which is an utterance that is particularly resonant and offers powerful analytic influence to a study (Smith, 2011). The gem, 'still no cure', will also be discussed.

Each super-ordinate theme and related sub-ordinate themes are presented in turn, accompanied by extracts from participants' transcripts. The particular extracts are selected because they provide the most coherent expression of the particular theme, while remaining representative of the entire sample. Participant names are replaced with a number to protect anonymity.

### **Feeling different**

The first theme encompassed ideas presented by the participants about their perception of their identity; specifically in reference to the effects that the insulin pump has on it. All participants spoke about their identity in some capacity. Throughout the participants' accounts, there was an underlying acknowledgment that, regardless of the insulin pump, diabetes affects identity. In terms of the insulin pump itself, participants gave ambivalent accounts, describing mixed feelings about it. Feeling that the pump threatened their identity on the one hand and protected it on the other.

### ***Threatening identity***

Participants talked about other people's curiosity about diabetes in general, which undoubtedly drew attention to them. They described the ways in which this uninvited attention made them feel; and yet there was no question that they have to

explain themselves to others, whether they invite the curiosity or not. Participants acknowledged that the pump invited curiosity due to its novelty, and was therefore a further threat to their identity as it exacerbated feeling different, which seemed to be a negative for them.

This participant reflected on people asking questions about her diabetes, in particular about the marks on her fingers from taking blood tests. The use of the word 'holes' seemed to suggest an element of pain or permanence.

*"...and they would ask why I have loads of holes in my fingers" (P1, 583<sup>1</sup>)*

She talked about how other people's curiosity made her feel and referred to the frequency of these events. It felt hopeless in the sense that perhaps other people might never understand it.

*"...sometimes it gets annoying, cos you've told so many people like so many times you would think they would know" (P1, 613-614)*

This participant reflected on diabetes in general, making reference to fitting in, and feeling the same as other children. It seemed that diabetes had changed how she saw herself in the context of normality.

*"...my life has changed completely, I'm not like any other kid, anymore..." (P4, 33-34)*

### ***Protecting identity***

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<sup>1</sup> Participant Number and Line Number

Participants talked about the pump as a protector from the threat that diabetes made to their identity. Particularly in relation to fitting in and the fact that diabetes made them feel different, the pump seemed to help protect their identity from this threat.

These participants made direct references to fitting in socially with peers, and how the pump facilitated that. Previously having to be removed from the group in order to inject insulin, but now no longer needing to do that.

*"...it's easier than having to go somewhere in private [pause] you can just like stay there with your friends" (P1, 647)*

*"...you kind of fit in better as well...and it just looks like a phone..." (P2, 855-858)*

*"I just felt like a normal person again and I could go out and play with my friends and I wouldn't have to worry about anything [pause] and I felt like I was free...." (P4, 184-187)*

There were also references to fitting in with family.

*"I can have ice creams now, like my sisters... and I won't feel left out" (P1, 660)*

And this participant makes reference to the idea that diabetes had caused her to somehow lose her identity within the family but the pump allowed her to feel like a 'daughter' again.

*"It makes me feel, like, ...I'm just their daughter, and I'm not anyone else." (P4, 362-363)*

Despite the visibility and novelty of the pump posing a threat to identity, the following participant suggested that its visibility actually protected her identity as a child trying to fit in. She made reference to people's perceptions of it and made powerful use of the word 'dangerous' suggesting that previously other people may have been 'scared' of her diabetes or of her; but that the pump protected her from this.

*"...with this like people have seen it, so [pause] they [pause] like em [pause] the pen looks kinda like dangerous and stuff like that and doesn't look the nicest to be honest, but the pump it looks, good and stuff like that, and, it doesn't look dangerous at all."*  
(P2, 583-587)

This participant referred to the pump as enhancing her choices about whether people know she has diabetes or not, the pump therefore enabling her to protect her own identity.

*"...its pretty well disguised, they don't actually realise I'm diabetic... It makes me feel a lot more confident, and I don't need to tell them if I'm diabetic or not..."* (P4, 252-258)

### **Grappling for Control**

'Grappling for Control' in relation to the children's perceived locus of control was a theme that was evident in all accounts. Participants made reference to their own role in the management of their diabetes, other people's roles; and ultimately the pump's role. There was ambivalence in relation to responsibility for diabetes, from wanting

to take responsibility to being scared about that. It seemed that the insulin pump contributed to both sides of this internal conflict.

### ***Internal Locus of Control***

These participants made reference to the pump as somehow enabling them to take more control, and therefore building their internal locus of control. There was frequent use of the word 'control' and it seemed that the pump enabled them somehow to feel that they could take some control over their diabetes.

*"...it feels, like I'm in control more" (P1, 112)*

*"...it's a lot more controlled, you have more control, ... because it's, I think it's easier to monitor..." (P2, 678-683)*

This participant simply spoke about positive emotions related to his role in using the pump.

*"I like doing, like, I like putting the thing on my arm and that and I like pressing the buttons and putting in the insulin..." (P3, 726-727)*

### ***External Locus of Control***

Given the age of the participants it was not surprising to hear frequent reference to the role of others in their care, in particular parents and health professionals. It seemed that the pump replaced the role of others for the children, and became a new source of external locus of control for them. Despite the pump enabling participants



to take control or responsibility for certain aspects of their care, in many ways it also worked to the contrary. Overwhelmingly, participants referred to the pump as an external being, through use of the word 'it' suggesting that it existed as a complete entity that stood alone separate from them, and could therefore take responsibility for their health.

*"...it's made me a lot more healthy and allows me to do a lot more things" (P5, 685-686)*

There was also a feeling that the pump was 'clever' and wouldn't make mistakes.

*"...like because the pump knows what its doing and [pause] when I go out to play, it won't give me insulin and that." (P3, 797-798)*

*"...if I feel ill, it'll just correct my sugar and keep on correcting it until it goes down ..." (P4, 310-312)*

One participant made a very powerful reference to the pump having the power and responsibility to save her life, suggesting her awareness of her morbidity and fear that she could die due to her diabetes. It seemed that the pump removed this fear.

*"...because I've got this thing and I don't need to, like, em, be brought home early because [pause] I might die during the night..." (P4, 205-207)"*

### **Better...**

The final theme to emerge was simply in relation to the fact that all participants described the pump as 'better'. They used their previous experience of injections as a

frame of reference and there was no doubt from any participant that the pump was 'better' than injections. However there was a feeling that there was a silent 'but' that followed this description, hence the use of the ellipsis...

### ***Better than jags<sup>2</sup>***

Participants compared features of the pump to their experiences of injections, and acknowledged the improvements, often related to flexibility, convenience and time.

*"It's [pause] better than injections" (P1, 816)*

*"...the pump is a lot faster as well, whereas...It means that we get to get out to play more and stuff like that, and we don't have to stop as much..." (P2, 741-744)*

*"...better...because [pause] em [long pause] because, you don't have to do jags all the time" (P3, 958-963)*

There were also frequent references to the simplicity of the pump; the idea that all they need to do is 'press a button'. This seemed to relate to the previous sub theme of external locus of control and feeling that the pump has the capacity to look after them, whilst acknowledging that they need to enable it to do that, by 'pressing a button'. The use of the word 'just' suggested the simplicity and ease of use while minimising their role as only pressing a button and the pump does the rest.

*"...but now we can cos I can just type it in and it's, helps" (P1, 117-119)*

*"...its made a difference... with the pump its always attached to you, ... you can just eat something and then just click a button..." (P2, 657-671)*

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<sup>2</sup> Injections

*"Well, like, you, just press [pause] like buttons and that, then the insulin goes in and [pause] that's it." (P3, 297-298)*

### **But not perfect**

There was a distinct sense from participants that although it was certainly 'better...' than injections, it wasn't perfect. There seemed to be a disconnection between their expectations of the pump, and the reality of some of the difficulties. Pain came through as the main drawback of the pump, specifically in relation to set changes (changing the cannula), which needed to be done in every two to three days.

*"...it's quite a big deal to get in for me, cos I get scared that it's gonna hurt" (P1, 194)*

*"Well, it was kind of like, sore all the time, just sittin there, ..." (P3, 183)*

*"It was sore, it was sore when the insulin went in..." (P4, 177)*

This participant gave a powerful account of the pain that she experienced, with reference to fear of losing the pump, or somehow losing the capacity to want to keep it. It felt as though she did not trust in her own ability to make decisions about her health or understand that she is in control of her own decisions regardless of external influences on them (such as pain). This resonated with the previous theme of *Grappling for Control*.

*"I'm, like, I'm scared it's gonna hurt, so much that I'll never want to do it again" (P1, 884)*

These participants gave ambivalent accounts of pain incurred using the pump, suggesting that it's not always sore, or perhaps they are still getting used to the pain.

*"Well it wasn't sore but it was just a wee bit sore. (P3, 325)*

*"sharp, kinda like, quick, about five, ten seconds and then it goes away... sometimes..." (P5, 324)*

The ambivalence that resonated throughout all accounts partially seemed to relate to the ages and stages of the participants. They often gave ambivalent accounts that felt in some ways that they had not thought about certain issues before, or that they were not particularly bothered. There were also occasions where they struggled to articulate how they felt; again perhaps because they had not thought about it before.

Smith (2011) refers to the idea of gems as having significance that is disproportionate to their size and although may only be a small extract from one account, they can resonate throughout a group of participants as a whole. He places gems on a spectrum from shining to secret. The following extract was interpreted as a 'shining gem' from one participant's account that seemed to resonate throughout the others.

*"It's good...well, better" (P1, 724)*

*"...what would it take to be good then, if it's better just now?" (Interviewer, 738)*

*"Em, if there was a cure for diabetes." (P1, 741)*

## **DISCUSSION**

In line with previous research, the current study supports the idea that children are able to identify both advantages and disadvantages of the insulin pump (Olinder *et al*, 2007; Low *et al*, 2005), and certainly the consensus remained that it was perceived as being better than injections.

Ambivalence seemed to encompass the participant's experiences of the insulin pump, expressed as an oscillation between the perceived benefits of the pump and the drawbacks. In part, this could be viewed as taking a balanced view of their situation, but the general feeling was more that the experiences represented a conflict within the children, rather than equilibrium. For this reason the main theme of the results was summarised as 'Developing a Relationship with the pump'; with the emphasis on the word 'developing', presenting it as a process. Ambivalence has been found in qualitative accounts of adolescent's experiences of type 1 diabetes (Dickinson & O'Reilly, 2004) and experiences of other conditions such as inflammatory bowel disease (Reichenberg *et al*, 2007). The current study does not show that children are more ambivalent towards insulin pumps than other regimes, but just that they are ambivalent towards the pump, suggesting that it may be indicative of an ambivalent relationship with diabetes itself.

In this study, the first super-ordinate theme was in relation to identity. Along with managing the demands of diabetes, children and adolescents have to manage ordinary developmental tasks such as developing a sense of self (Dovey-Pearce *et al*, 2007). The aim of this study was not to explore the developmental intricacies of growing up with diabetes, and certainly the ages and stages at which children reach

developmental milestones is likely to be different even across this small relatively homogenous sample. Diabetes has been shown to have an impact on personal identity and self-concept and can cause young people to question and redefine themselves in relation to others and their future (Dovey-Pearce *et al*, 2007). Fitting in with peers as opposed to standing out or being watched has been shown to be important to children with diabetes (Dickinson & O'Reilly, 2004). The findings showed that children considered their identity in relation to feeling different and having restrictions; and therefore the ways in which the insulin pump contributed to these factors either threatened their identity or protected it. It seemed that the insulin pump was certainly capable of both tasks, and took both roles for many of the children.

The second super-ordinate theme was related to control. Research has shown that children aged 8 to 19 years, who have more of an external locus of control, have better glycaemic control, indicating that assistance can be an asset (Weist *et al*, 1993). More recently Nabors and colleagues (2010) found that children aged 8 to 15 who had a higher internal locus of control had better glycaemic control. However they also found that children who had lower internal locus of control, but had a positive attitude towards their illness were likely to have better glycaemic control (Nabors *et al*, 2010). The accounts of the children in this study oscillated between internal and external locus of control. It seemed that the insulin pump more frequently contributed to the children's external locus of control, but this was not necessarily representative of poor glycaemic control, in line with previous research findings. The pump seemed to facilitate the children's own sense of control, perhaps being perceived as taking on the role of a parent or helpful health professional for the child.

The third super-ordinate theme was in relation to the practicalities of day-to-day life with the insulin pump, perhaps related to quality of life. Children were able to identify both benefits and drawbacks of the pump. Benefits tended to be in comparison to injections, and overwhelmingly the accounts suggested that there was 'no competition'. The overall feeling was that the benefits outweighed the drawbacks in their appraisal of the pump. However the drawbacks served as a reminder of the underlying struggles with diabetes in general and affected their attitudes towards the illness itself, which may in turn link with and affect their locus of control negatively and ultimately their glycaemic control (Nabors *et al*, 2010).

The final 'gem' that emerged was in relation to the fact that there is no cure for diabetes. Regardless of how the children experienced the insulin pump, it could not remove their diabetes, although it might improve some of the symptoms and consequences of diabetes. Diabetes in children and adolescents is fraught with opposing demands: on the one hand children are exposed to increased responsibility to care for their health and on the other, their condition can make it harder for them to progress to independence (Carroll & Marrero, 2006). It felt as though much of the children's overall ambivalence that came through in their accounts, was in fact related to diabetes itself. A move towards developing an acceptance of diabetes is therefore likely to facilitate a move towards a resolve of this ambivalence.

### **Strengths and Limitations**

The current study is the first in the UK, to the author's knowledge, to explore the experiences of CSII in children and their parents using IPA methodology. It adds to the existing, albeit small, evidence base that exists and it contributes to health care

workers' understanding of the ways in which the children they care for, experience this treatment.

Only 5 children participated, limiting the generalisability of the findings. The pediatrician's involvement at the recruitment stage could potentially have constrained disclosure and discussion. The researcher did not take into account the type of pump, which could have affected the children's perceptions and opinions about treatment e.g. tethered or un-tethered and the difference this could make to issues around visibility and flexibility. The study also did not specifically address the duration of diabetes (other than to meet inclusion criteria). Two children in particular had been diagnosed very young, which may have affected the ways they experienced treatment. A meta-analysis of insulin pump studies found that subjects with a shorter duration of diabetes were more likely to discontinue pump therapy (Weissberg-Benchall *et al.*, 2003), however a more recent study failed to find such a difference (de Vries *et al.*, 2011). McMahon *et al.* found that a shorter duration of diabetes correlated significantly with better glycemic control however Shalitin *et al.* found no added benefit to glycemic control for starting pump therapy at an early disease stage (Shalitin *et al.*, 2012). The study did not consider co-morbidities and some of the children could have been coping with additional illnesses/conditions at the same time as managing diabetes.

## **Conclusions**

This study adds to the understanding of children's experience of CSII by building on previous findings, through a more in-depth analysis. It seemed that children between the ages of 8 and 14 had an ambivalent attitude towards the insulin pump



as they attempted to develop a relationship with it; which was hypothesised as being symbolic of their relationship with diabetes. Further research could consider further the issue of locus of control and perhaps make use of standardized measures. Further research could also explore health care practitioners experiences of managing families with CSII.

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## **3.5 RESULTS**

### **3.5.1 Introduction**

The aim of the current study was to explore the experience of insulin pumps for children with type 1 diabetes, and their parents. The child and parent accounts highlighted both positive and negative experiences associated with this treatment and with diabetes in general. The child and parent interviews were analysed separately; and as such the results are presented and discussed separately.

The following section will focus on the results of the parent interviews.

### **3.5.2 Parent Interviews**

The analysis produced 15 sub-ordinate themes and these were subsumed within five super-ordinate/master themes: *(1) Parenting a Child with Diabetes; (2) Worth the Hard Work; (3) Strive for Normality; (4) The Pump as an Enabler; and (5) An Eye on the Future.*

A summary of the super-ordinate themes and related sub-ordinate themes are presented in table 3.4. The next section will present a detailed description of each super-ordinate theme and sub-ordinate themes making reference to illustrative verbatim quotations from the participant's transcripts. These particular extracts were selected to provide a coherent expression of themes, whilst representing the individual views across the sample. The extracts are from fully anonymised transcripts, with the source of each quotation indicated by the participant's assigned participant number.

**Table 3.4 Summary of Super-ordinate themes and Sub-ordinate themes -  
parents**

<b>Super-ordinate Themes</b>	<b>Sub-ordinate themes</b>
Parenting a Child with Diabetes	Feeling Powerless Coping with Uncertainty Getting it Right Other People Don't Understand
Worth the Hard Work	Expectations Vs. Reality Hard Work Just Press a Button Worth the Effort
Strive for Normality	The Same but different A New Normal
The Pump as an Enabler	Practical Enablement Psychological Enablement
An Eye on the Future	Looking to the Future with Hope A Cautious look to the Future Fear of Losing the Pump

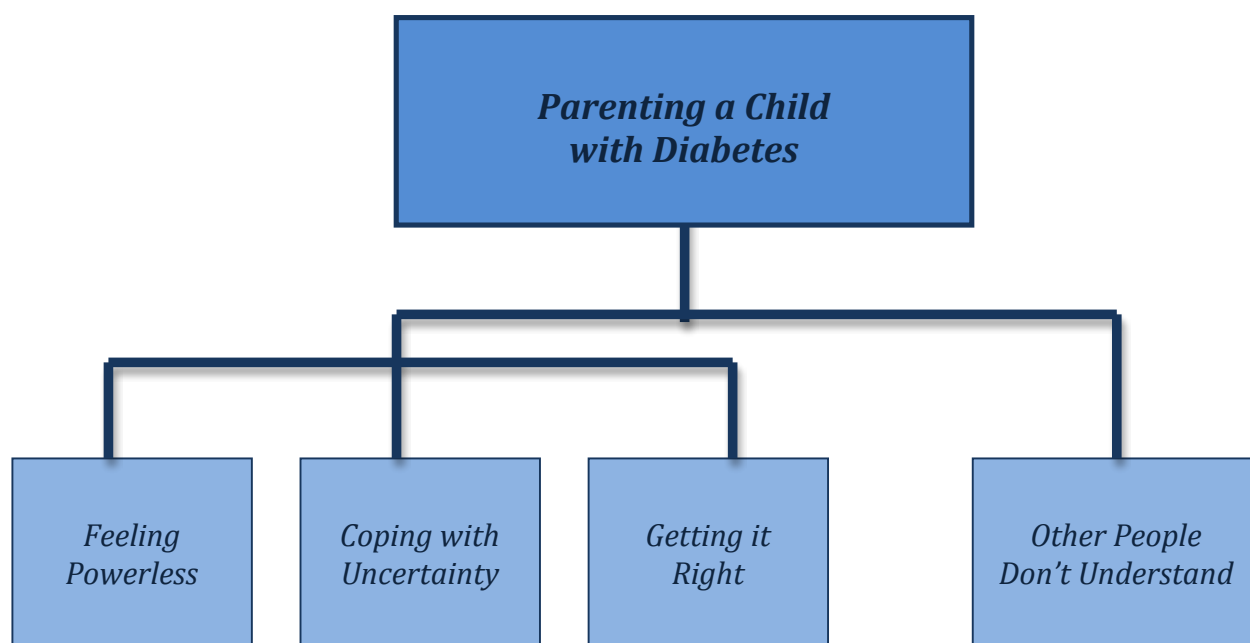
Smith *et al.* (2009) recommend when analysing data from larger samples (more than six participants) that there should be a connection between themes, to help the data move

to a more theoretical level. Despite this particular section considering only a sample of five, throughout this section the researcher will hypothesise about potential connections between themes as they emerge.

### 3.5.2.1 Parenting a Child with Diabetes

The first super-ordinate theme, “Parenting a Child with Diabetes”, describes the parent’s experiences of parenting their child and covers the periods of time before and since the insulin pump. Participants described a number of different aspects associated with parenting a child with diabetes. The four sub-ordinate themes contained within this were: *Feeling Powerless*, *Coping with Uncertainty*, *Getting it Right*, and *Other People Don’t Understand* (see figure 3.2).

***Figure 3.2 Sub themes associated with ‘Parenting a Child with Diabetes’***



### *3.5.2.1.1 Feeling Powerless*

Parents spoke about feelings of powerlessness when it came to their child's diabetes. These feelings varied across the sample from feeling powerless towards diabetes itself. This parent implies that there is something special or unique about diabetes in relation to powerlessness.

*"I think its just diabetes, when its [pause] as a family it changes your whole life... its amazing how much it consumes your life actually" (Parent 3, Lines 900-904)*

And reflecting on how these feelings of powerlessness translated for them. One parent reflected on his child's distress towards her diabetes and how that made him feel:

*"Absolutely distressing, you know, its terrible, its bad enough, if it's something that happens to you but to listen to her saying that, and you feel there's absolutely nothing I can do" (Parent 4, Lines 69-71)*

This particular parent also reflected on the effect that these feelings of powerlessness were having on his wife also. It seemed as though he was feeling powerless towards his daughter's diabetes while at the same time trying to contain his wife's feelings. This highlighted the impact that some of these feelings can have on families and relationships.

*"Mum's still, even, today, she'll turn around and say "I don't want my daughter to be diabetic" {mm hmm} "I don't want (child's name) to have this" you know, and she knows, obviously that there is no, alternative, there's nothing we can do about that"*  
(Parent 4, Lines 84-87)

Parents spoke about feeling powerless towards the treatments for diabetes, in particular when they reflected on their experiences with insulin injections. The use of the word 'abused' in the following extract is a powerful example of this.

*"...she was being abused by, the amount of injections she was getting"* (Parent 2, Lines 422-423)

*"...he sometimes say "aw I wish I didn't have these injections" or {right} you know, just, sometimes he was a wee bit down"* (Parent 3, Lines 98-100)

Another parent reflected on her feelings towards her child's glycaemic control. It seemed that parents felt responsible for improving their child's glycaemic control, and yet they were very aware that there could be lots of factors that contribute to this that are out with their control.

*"...we kept looking, and we were sort of trying all these different things and, it sort of in despair really"* ( Parent 5, Lines 129-130)

The feelings of responsibility from this particular parent were very powerful. She described how this intense feeling of responsibility, for something that might be out with her control, made her feel emotionally and physically.

*"...you just feel so dreadful, and [pause] and you'd feel awful, you know, until you could get him sorted, till his level was down later in the day, and then, sometimes you know, it was, I wouldn't get him down until you know, maybe, after school or something, and you just feel so sick, you'd feel sick because you'd know your child, wasn't well and you knew you were the only one that could sort it out, and you just felt all this responsibility but you didn't know how to fix it {mm hmm} and, oh it was just horrible, really really horrible." (Parent 5, Lines 594-600)*

#### **3.5.2.1.2 Coping with Uncertainty**

The feelings of powerlessness, that were evident in many parent's accounts, often translated to having to cope somehow with uncertainty. Coping with uncertainty was something that seemed to be necessary when parenting a child with diabetes. Parents tended to associate their uncertainty with their child's glycaemic control, perhaps because that was something that was very visible to them.

*"...even, trying to stick with that, kind of strict routine, her levels were still, still too high" (Parent 1, Lines 27-29)*

*"Can't get any rhyme or reason to it, sometimes I think maybe, she's, tired, it's the time of the day, is she hungry, is she low, but there's not, there's just not any one thing" (Parent 1, Lines 385-387)*

*"...his readings would go sky high and we just couldn't understand it, because, we knew it wasn't food and we knew the exercise was sort of, and we just couldn't understand it and then once he started to go high, he'd have this resistance and you'd keep having to give him more and more insulin, and it would take him another day to get back to normal, and by that time we were giving him loads more insulin which wasn't right." (Parent 5, Lines 145-150)*

This parent was able to reflect that although diabetes brings uncertainty to the person who has it, and their family; this uncertainty can also be felt within the wider system of care.

*"...the readings were all over the place [pause] I just, I didn't know what was going on, and, the team, you know, although they were trying to help, they didn't know either." (Parent 5, Lines 225-228)*

One parent reflected on the uncertainty that was around for her child prior to the insulin pump.

*“...before the insulin pump it was very erratic” (Parent 3, Line11)*

*“...before it was just em, because some, some foods that he’d eat maybe spike, so it’d have a big high, a big sugar rush” (Parent 3, Lines 291-292)*

However she could also realistically acknowledge that the feelings of uncertainty came not just with insulin but in fact were part of diabetes, as she reflects here on his glycaemic control following the insulin pump and the effects it has on other aspects of his life.

*“...when he is high, and he’s angry and he, he just gets frustrated with anything, he takes it out on anything” (Parent 3, Lines 392-393)*

Despite the uncertainty that can come with diabetes, this parent seemed able to reflect on the fact that it is the acknowledgement and the acceptance of the uncertainty that actually allows you to begin to cope with it.

*“...but that’s why its quite hard, cos there’s no constancy” (Parent 5, 726-727)*

*“...its just taken a long, you know its been a long learning process, cos even though we thought we understood it all to begin with {uh huh} um, it was the unknowns, that, you know, it doesn’t sort of tell you, in the, in the journals and things” (Parent 5, Lines 838-841)*



The previous sub-themes related to powerlessness and dealing with uncertainty felt particularly powerful. There was a real sense of feeling victimized and out of control at times and certainly overwhelming responsibility of parents. A feeling of responsibility, which was potentially exacerbated by the next theme.

#### *3.5.2.1.3 Getting it Right*

Despite acknowledging feelings of powerlessness and uncertainty associated with parenting a child with diabetes, there was an overwhelming feeling of responsibility from all parents, for their child's health, through the management of their child's diabetes. This responsibility for their child's diabetes seemed to be an ongoing battle for parents; a war between them and diabetes. Although the parents were good at acknowledging the extraneous variables that played a part in their child's diabetes control, and ultimately in their child's health, it still felt as though, to them, it was something that they could either get right or wrong.

*"...dealing with it all, trying to regulate the ratios, as I said because she was on such high doses of insulin, trying to get it right" (Parent 2, Lines 256-257)*

These parents reflected back somewhat regretfully on life before the insulin pump and their approach to their child's diabetes.

*“...we weren’t strict enough because our, our, we kinda had developed, probably not such good habits [pause] eh as she became older” (Parent 1, Lines 75-76)*

*“And you know we made mistakes, we did make mistakes, we were [pause] you know, we should’ve given him more insulin, and we were too nervous, but it was difficult” (Parent 5, Lines 256-259)*

One parent went on to describe how things could still go ‘wrong’ even whilst using the pump. She made use of the word ‘we’ in reference to herself and her husband; and there was an underlying feeling that perhaps they had hoped that the pump might have taken some of the overwhelming responsibility from them; and the almost hopeless acknowledgment that it didn’t.

*“It was, It was hard. em, it was disappointing. [pause] but, it was kinda worrying as well, that even [pause] kind of just facing up to the fact that even with the pump, we weren’t getting her levels [pause] where they should be” (Parent 1, Lines 204-206)*

This parent reflected on stressful feelings of pressure and responsibility to achieve diabetes control for his child.

*“...there’s a real pressure on you to, to achieve control” (Parent 4, Lines 75-76)*

#### *3.5.2.1.4 Other people don’t understand*

Feelings of isolation or being on their own with diabetes seemed to underlie some of the parent's accounts. Although all parents made reference to external supports either from wider family systems, or the health care system, there was a feeling from some accounts that other people didn't fully understand what it was like.

*"I think because it is quite complicated, nobody else can really get their head round it" (Parent 5, Lines 805-806)*

This parent made reference to her frustration that other people didn't understand the complex difficulties that her son faced with his diabetes.

*"...cos he's just a number that its frustrating, every single year when he changes teacher [pause] they just don't get it, they don't get that if he's, high he wont take in any of the lesson, they, they just don't get it" (Parent 3, Lines 377-379)*

*"...they just think that he's got diabetes, he eats and you give him injection, that's what they think. They don't think how it affects him" (Parent 3, Lines 390-391)*

She went on to describe how she tried very hard to contain this frustration or worry from her son. She acknowledged that he himself had started to worry that other people didn't understand his diabetes, but that she felt she had to reassure him that they did, even although she didn't believe that they did, to protect him and contain his anxiety.

*"Yeah, they just phone me up to, to maybe check some things, but, I just keep saying  
"see, they know what they're doing, they're getting really good at it" [laughs] and  
maybe they're not, they're just not getting it" (Parent 3, Lines 887-889)*

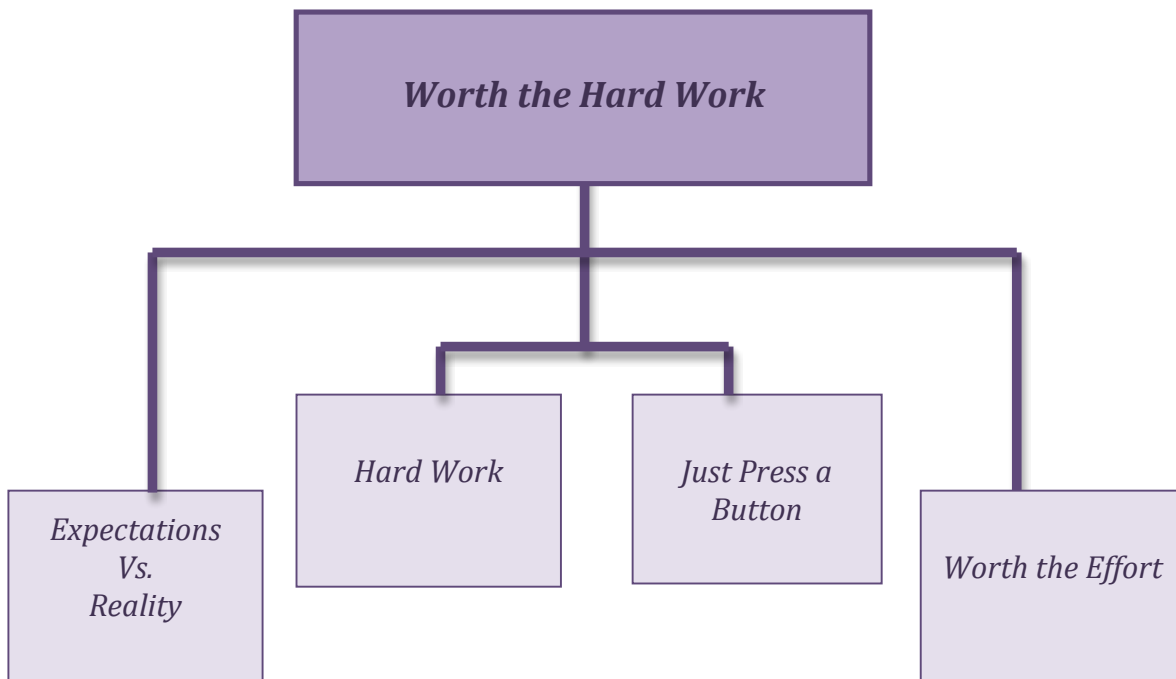
This parent made reference to the fact that other people are nervous around her son, because they don't understand how to manage his diabetes, which relates back to the previous theme in relation to increased responsibility for the parent if other people don't understand.

*"So you really really have to spell it out to people and sort of write things down,  
and, people get a bit nervous," (Parent 5, Lines 820-822)*

#### 3.5.2.2 Worth the Hard Work

The second super-ordinate theme, 'Worth the Hard Work' relates to the parents' accounts of life with the pump. Part of the parents' accounts covered life immediately before the pump and the anticipation and expectation that was experienced at this time. However the parents gave complete and honest accounts of life with an insulin pump and part of these accounts acknowledge that the reality of the insulin pump did not always match their initial expectations. The overwhelming feeling throughout all parent interviews was that no matter how they experienced the actual reality of the insulin pump; whether it was hard work or different to what they had expected; all families described it as being 'worth it' on balance.

**Figure 3.3 Sub themes associated with ‘Worth the Hard Work’**



#### *3.5.2.2.1 Expectations Vs. Reality*

There was an overwhelming feeling from the parent’s accounts that the pump was sought after and certainly wanted.

*“...you know, there was no question, if they were prepared to give (child’s name) a shot of it, em, we were all willing to, to have a go and see how we, how we got on with it” (Parent 5, Lines 143-145)*

*“We couldn’t wait for her to get the pump” (Parent 2, Line 321)*

Parents reflected on their children’s expectations and desire to get the pump.

*"...when he was at his week away at (diabetes camp) he would see people on the pump then he would start talking about it and then he wanted to try it" (Parent 3, Lines 171-173)*

*"(child's name) looked up the treatment of diabetes and come up on insulin pumps and she's turned around and, within a few days, and said I want one of those things" (Parent 4, Lines 25-27)*

This parent reflected on the lengths that they might have gone to in order to secure an insulin pump for their child. Highlighting the extent of how *wanted* it was for them.

*"...we, we at that point thought we were gonna have to try and fund this ourselves, em, we actually did some sponsorships and stuff started, to start getting the pump cos we wanted the pump for her" (Parent 2, Lines 330-332)*

In terms of expectations, parent's reflected on feeling hopeful and positive towards getting the pump and about what they thought it could do.

*"Oh I though it was, gonna be fantastic, I mean, I, we were, right in thinking that" (Parent 1, Lines 149-150)*

*“...from adults to children cos obviously there was a lot of children had the pump and they were saying how great it was in their experience, and since the minute she saw it on the internet and it explained what it did, she had a fair idea what a pump was before em, but em myself and my husband sorta telling her, just the gist of it, what it would do for her, she just was hooked” (Parent 2, Lines 218-223)*

*“...we, sort of hoped that the insulin pump would make it easier because the dosages would be more accurate” (Parent 5, Lines 30-31)*

Yet, there were often conflicting accounts within families associated with the reality of getting the pump. The reality of life with the pump, contrasted with the positive expectations they had prior to getting it. Some parents went on to reflect honestly on how the reality of the pump turned out to be different to their expectations, to the extent that they almost gave up on it, or lost it. These feelings seemed to tap into the idea of ‘getting it right’.

*“...and it was disappointing, but [pause] not because he was gonna take the pump away, which would have been a long way away, but just the fact that we, her levels were so bad, that that was something that they could even consider at that stage, that the point of the pump was to get the levels down and it just wasn’t working.” (Parent 1, Lines 235-240)*

*"I mean, for a while [pause] in the winter there, when he was running high and I knew we'd sorted out the site thing, and he was just so high, em, I wanted to go back to injections {ok} um, but my husband said absolutely not, but, I [pause] just you know was at my wits end cos he was running so high" (Parent 5, Lines 529-533)*

This parent made reference to the difficulty of changing the cannula from which the insulin is delivered (set change), and it seeming like perhaps this was a difficulty that they had not considered prior to getting the pump.

*"...although the advantages are, are great, that, at that point we were really, struggling, that was the point when we were thinking, we, no this is just not working for us, because it was such an issue, to get the sets changed" (Parent 1, Lines 712-715)*

*"I remember one very frustrating day, when we were on holiday in France and we spent hours, by which time the whole family was completely wound up, everyone was shouting at each other, everybody's completely stressed, cant go anywhere, cant do anything until she's got this bloomin thing in" (Parent 1, Lines 311-315)*

This parent also reflected on features of the pump that perhaps they had not considered prior to actually getting it.



*“...fixating on the pump being in and the pump actually working, um, is an added worry, its something that’s come in, that wasn’t there before” (Parent 4, Lines 453-455)*

This parent talked of how her child’s expectations did in fact match the reality of the insulin pump for them.

*“...because she knew herself it would just take away all the hassles that she has with all the injections [pause] em [pause] [laughs] and she, she what, well when she got it she just loved it” (Parent 2, Lines 224-226)*

This parent acknowledged her awareness of the fact that other people perhaps have the same expectations that she herself had initially, an expectation that the pump is simple or that it reduces responsibility, and she makes reference to her acknowledgement that it is not through her emphasis of the word ‘no’.

*“...you think, everybody thinks “oh that’s great, you don’t have to, all you have to do is, you know, it just works it all out for you”, and “nooo” you know” (Parent 5, Lines 806-808)*

#### **3.5.2.2.2 Hard Work**

The contrast of prior expectations vs. actual reality emerged into a real acknowledgment of just how much work was involved with the insulin pump. Although there were contrasting experiences of how expectations met reality, several parents acknowledged the reality as being 'hard work'.

*"...then, the pump came along, and it was just, for a good long while, it was really, really hard, on everybody, you know, because we were getting really stressed about it that, screaming at the kids because, because we were just so wound up about it all the time and it really was becoming a big issue" (Parent 1, Lines 703-707)*

This parent's repetition of certain phrases in the following extracts seems to strongly acknowledge the amount of time that the pump consumes and the extent of the hard work.

*"...you still got to put a lot of thought in all the time, you're still thinking all the time, all the time" (Parent 3, Lines 958-959)*

*"It is a lot of, it has been a lot of work, um, it was a lot of work on the injections, and it was harder initially on the pump, because we had to try and tweak the basal as well [pause] {mm hmm} um, and also [long pause] um, its just, you know, it is harder, initially." (Parent 5, Lines 195-198)*

This parent went on to describe how herself and her husband tried to take on the work and shield their child from it. This again seems to resonate with the past themes of ‘getting it right’ and ‘dealing with uncertainty’ in relation to the parental responsibility.

*“Well it, its horrible. I mean we tried not to make it too difficult for him but you know it was just a constant, worry, for me and his dad, um, just constantly trying to [pause] look at his patterns and trying to work out what we could do to make it better,”* (Parent 5, Lines 167 – 170)

#### **3.5.2.2.3 Just Press a Button**

Despite the honest accounts of how much work is involved in managing the insulin pump, there was a feeling emerging from many of the parent’s accounts that there was still an element of simplicity to the pump. This idea of, no matter how much work it took, ultimately it boiled down to pressing a button.

This simplicity was compared with injections, which by comparison, parents tended to suggest were much less simple.

*“if she’s not feeling right [pause] and it’s because her level is too high, she can obviously do a test and, and correct it, straight away, rather than waiting until she’s due to do another injection [pause] rather than, sorta, sticking needles in herself half a dozen times a day, just wait till the next time when she was due an injection*

*anyway, and correct at that point. So it means that she's correcting, it, or has the ability to correct, much more often than she was, eh on, with the [pause] eh, with the injections."* (Parent 1, Lines 44-50)

*"...they can't comprehend how invasive it was on your life, em, and how just, remarkable it is now just to [laughs] press that button. Honest to god, pressing that button just, it makes such a difference"* (Parent 2, Lines 571-573)

This parent made reference at several points to the idea of 'just pressing the button'.

This simple notion seemed to sum up her experience of her child's insulin pump.

*"Out for a meal, carb count and press a button"* (Parent 2, Line 39)

*"...so its great knowing that you can just go out, you can just [laugh] eat, count and press a button {mm hmm} that is the great thing about it {yeah} and ok, you're pressing a button but that's all you're doing,"* (Parent 2, lines 430-432)

Parents made reference to the freedom that the pump gave them and their child. They often associated this freedom with eating and mealtimes and the flexibility that came with the insulin pump, that hadn't been there before.

*“...and then if somebody appears and brings a birthday cake, she can have a bit of birthday cake, and we can just instantly, adjust, to, to make up for it” (Parent 1, Lines 573-576)*

*“...it’s totally different on the pump, he can just [pause] I mean not, you wouldn’t advise him to eat and eat and eat all day but he could have something twenty minutes later and he just puts it into his pump rather than another injection” (Parent 3, Lines 106-109)*

*“...the pump keep, maintains her sugar reasonably well in a normal range and, you know if she doesn’t eat on time that’s not a big issue” (Parent 4, Lines 528-530)*

*“...whereas when the pump arrived [pause] that just went away, we didn’t have to worry anymore, work out how many carbs is in a meal [pause] and (name of child) tells the pdm to give her [pause] whatever insulin through the pod [pause] and its so much easier.” (Parent 4, Lines 408-411)*

#### *3.5.2.2.4 Sticking with it*

Parents were able to reflect on life since the insulin pump, and there was a very real acknowledgement that the insulin pump was hard work. However, overwhelmingly, the

accounts suggested that despite the hard work, despite the reality of the insulin pump (which may or may not have met their initial expectations); it was all worth it.

*“...we got over it, we somehow got through it, and, em, and now we wouldn’t change it for, for the world”* (Parent 1, Lines 724-725)

This parent acknowledges how difficult it is to articulate the experience of the insulin pump. Describing it as being somehow indescribable, and yet still positive,

*“I I can’t put it into words, how good it, how positive its been {mm hmm} its very, it’s all right for the right reasons.”* (Parent 2, Lines 456-458)

This parent makes reference to the loss associated with diabetes particularly with insulin injections; and by contrast the benefits associated with the pump.

*“...it to-, totally brought back our daughter”* (Parent 4, Lines 36-37)

These parents simply allude towards the benefits that are to be found, preceding the hard work that is necessary.

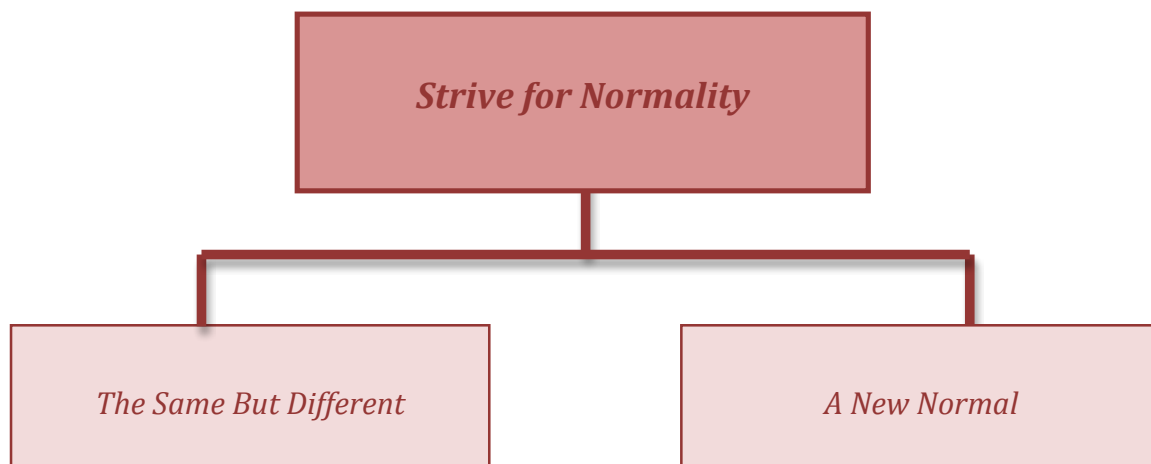
*“...em but bear with it cos it, it does work”* (Parent 3, Lines 819-820)

*“And its definitely the right way now, I know that, but, I think you just, it, you need a lot of time, to work things out, and [pause] yeah, it, its good, once you sort of master it.” (Parent 5, Lines 342-344)*

### 3.5.2.3 Strive for Normality

The third super-ordinate theme to emerge from the parent interviews was associated with ‘normality’. Parents somehow seemed torn between striving for a normal life, while realising that their child was in many ways different and needing to treat them that way. The pump featured strongly in this striving for normality as parents reflected on the ways that the pump aided this struggle.

**Figure 3.4 Sub themes associated with ‘Strive for Normality’**



#### **3.5.2.3.1 The Same but Different**

Parents described a conflict between attempting to treat their child the same as other children, while making real reference to the reasons that this might not be possible.

This parent reflects on the ways that she has tried to treat her daughter the same as other children. There is a sense of guilt from this parent as she reflects on the ways that this may not have been beneficial to her child. Again, this resonates with previous sub themes of ‘getting it right’.

*“But I think now, looking back, we maybe did [pause] eh, we were too, trying not to make too big a thing of the fact that she had diabetes, and make her too much like everybody else” (Parent 1, Lines 89-91)*

However, there are times in the parent’s accounts where they try to fit their child’s diabetes regime into the context of routine family life, in attempt to normalise it.

*“Its just, that what we’ve done, twelve years its routine, it, you know it’s [pause] its almost like, kinda, we have to wash their face and brush their teeth, and (child’s name) has to, has to do this as well, its just an extra thing and we just now had it for so long” (Parent 1, Lines 482-485)*

*“...we’re not restricting her to anything we wouldn’t restrict the other [pause] children to” (Parent 4, Lines 212-213)*



These parents made reference to the differences between their children and other children. The differences seemed to be in relation to freedom and independence, alluding to their responsibility as parents to harness these concepts.

*“...they’ve not got the same freedom as other children” (Parent 3, Line 46)*

*“...you know, its complicated and we, we cant give him quite the independence that some of the other parents do” (Parent 5, Lines 703-705)*

There were conflicting accounts from parents between internalising diabetes and the insulin pump as part of who their child is,

*“...it’s part of him, he just thinks that’s his pancreas on the outside of his body, that’s what he thinks. Its part of him, he doesn’t think it’s [pause] its anything unusual. To him that’s just, like having an arm or a leg” (Parent 3, Lines 182-184)*

*“...yeah like the other kids don’t, don’t think anything of it, they don’t play about with it or anything, that’s just part of him” (Parent 3, Lines 621-622)*

to externalising it and seeing it as separate from their child,

*“And the other thing we have to take great care of is, eh [pause] not fixating on the diabetes constantly and seeing [pause] her, rather than “hi, what’s your sugars today” {yeah} you know.” (Parent 4, Lines 93-95)*

This parent made reference to the fact that other people see her child as being different, and she battles with protecting him from that in her strive for normality.

*“...before I would just inject (child’s name) at the table cos I don’t see why I should have to hide it, don’t see why, I’m not taking him to a toilet to do it, em [pause] but the people would stare, I mean we’ve had people at a [pause] play area [pause] you know dragging there children away, like “that boys not well”, and its “he’s fine, he’s alright, there’s nothing wrong with him” so, you don’t have to deal with peoples negativity about being diabetic” (Parent 3, Lines 756-762)*

In their acknowledgement of the differences in their children, some parents associated the differences with the concept of disability. This parent powerfully made reference to her child’s mortality in association with diabetes, and somehow it seems that this is a constant reminder for her that her child is different.

*“...obviously it’s a hidden disability so nobody sees that, the work that you have to do {yeah} to keep him alive basically” (Parent 3, Lines 945-946)*

This parent describes what sound like a genuine effort to keep his child the same as other children and tries to disregard the notion of disability. Disability seemed to highlight difference for this parent.

*“...what we always tell her is, you know, one thing we’ve taken care of, great care to is not see her, let her see it as a disability {mm hmm} technically [pause] if you go by the law then, things, then it is a disability [pause] but eh, we’ve, we’ve refused to let her be labelled as a disabled child, and we don’t want her to live the idea that it is a disability” (Parent 4, Lines 108-112)*

*“...we felt that very important to [pause] tell her she’s normal, she just happens to have diabetes {yeah} and eh, that it’s easily dealt with [pause] em [pause] as long as you, you follow things” (Parent 4, Lines 116-118)*

However he went on to describe the difficulty in imparting the idea of ‘same but different’ to his child, after the insulin pump came along. Wanting her to feel the same as other children, but needing her to realise that the differences were still fundamental. This ambivalence felt like it was difficult for them to resolve.

*“...the challenge was still to remind her, that even though, she can now have more freedom, she’s still a diabetic and she still needs to watch what she eats” (Parent 4, Lines 205-207)*

### 3.5.2.3.2 A New Normal

All parents reflected on the changes to their lives following the insulin pump. Although there were conflicting accounts in relation to their children being ‘the same but different’, there felt like an attempt from all parents to find some kind of normality. There seemed to be an acknowledgement however, that achieving ‘normality’ with a child who has diabetes is hard work. The insulin pump somehow enabled them to find some kind of ‘new’ normal.

*“Because [pause] she’s diabetic, she carb counts, before every meal [pause] but that’s part of life now [pause] but there’s no longer this “right come here to we get your injections done” or “have you got your needle set up for injections”. Its like that part’s not there anymore” (Parent 2, Lines 416-421)*

*“I don’t think she’s eating, vastly different things, from what she did when she had her [pause] when she had her insulin, eh injections, but I, I think it just means that she now has a much more of a control, because she can deal with it, instantly” (Parent 1, Lines 100-103)*

This parent made the very real comparison between what used to be normal and what now is normal, in terms of glycemic control.

*“...if she gets, you know, anything that’s twenty something, we’re absolutely horrified, but before, that was almost, the norm, {right} that’s where it was, it was as, as bad as that, we just couldn’t get them down, and where they should be, but now, now, literally if its in double figures, we’re, we’re disappointed,”* (Parent 1, Lines 663-667)

Although the idea of the extent of the hard work still resonated within this account, the fact that the family learned to accommodate the insulin pump as part of their daily lives, brought a sense of acceptance.

*“...for it being such a big part of our life, we don’t make it a big part of life, its just, something we have to do, she has to do it before she has her meals, she has to give herself insulin when she’s finished her meals, but, and we just, do it, and it’s just, done, and there’s no big, usually, no big fuss made about any of it, {ok} [pause] just get on with it”* (Parent 1, Lines 489-494)

Other parents also acknowledged that the idea that their child had adapted to life with the pump; the pump had found its place in the context of their lives.

*“...its just a part of our life and she just, does it, and gets on with it, and [pause] em, I think a lot of the time she’s not even aware [pause] that its there because she’s got so used to it {mmhmm} you know she puts on her clothes in the morning, and she*

*puts her pump on her belt and that's, that's it, then gets on with her day"* (Parent 1, Lines 797-801)

*"...its just all natural now {right} but it's so easy for her. And obviously she does it now a lot of the time without thinking."* (Parent 2, Lines 381-383)

*"No, see when you've got the pump, it's just a part of your life"* (Parent 3, Lines 895-896)

*"we've just got so used to it so,... it isn't really a big deal at meals anymore {ok} which is good"* (Parent 5, Lines 562-565)

Parents simply and directly spoke about the idea of getting back to 'normal' whilst acknowledging the differences that the pump has made (positive and negative); a sense of a 'new normal'.

*"...it just, again, it makes you appreciate how [pause] again, normal, the pump just makes life for you. "* (Parent 2, Lines 629-631)

*"Its fine now, its good now, its back to normal now"* (Parent 5, Line 577)

*"and certainly I can say the pump has made a great, great, great difference there {ok} you know cos it makes it a lot easier for her to fit in, and to see herself as being*

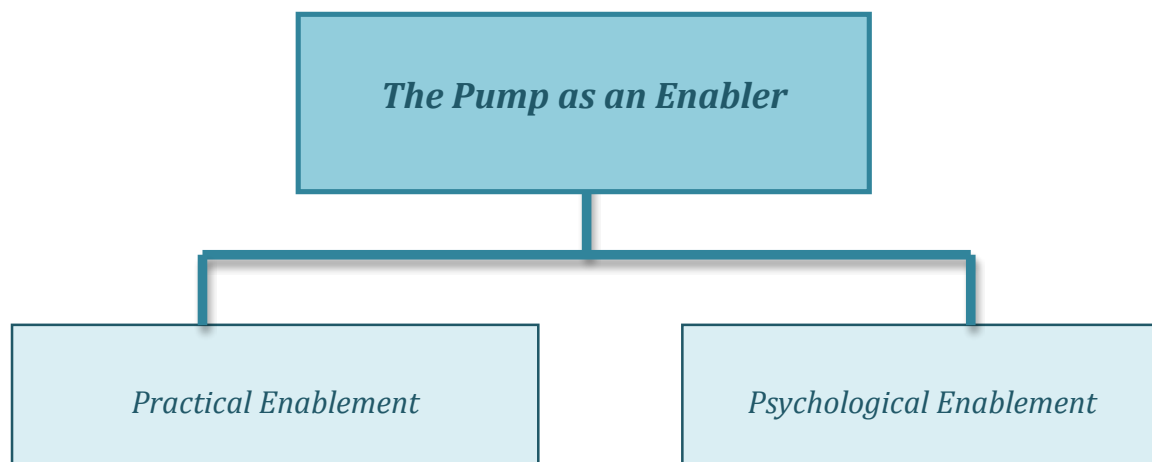
*normal {uh huh} just happens to have diabetes at the same time, I think” (Parent 4, Lines 119-122)*

*“...for us the pump just means, it’s almost as best as possible [laughs] we could get back to some sort of normal life” (Parent 2, Lines 24-26)*

#### 3.5.2.4 The Pump as an Enabler

The fourth theme, ‘The Pump as an Enabler’, came through in all parent’s accounts. This theme linked with the previous theme associated with normality. There was a feeling from many of the parents that the pump helped the families in their strive for normality, and enabled the idea of a ‘a new normal’. Certainly there were clear examples from all parents of the pump enabling their children and their families in very practical ways. Other families made reference to the deeper role of the pump in terms of enabling their children emotionally. In turn there was a real feeling that practical enablement enhanced psychological well-being and vice versa.

**Figure 3.5 Sub themes associated with ‘The pump as an Enabler**



#### 3.5.2.4.1 Practical Enablement

Parents provided clear examples of the ways in which the pump brought flexibility to their lives.

*"I, I, Its just, it's a bit easier, its {mm hmm} em [pause] it, it is, it does give us a lot more flexibility, she can go to her friends house, she can change plan and stay for tea, {yeah} she can stay overnight without having to come back home or for us having to nip down and take stuff down" (Parent 1, Lines 562-566)*

Flexibility seemed important to parents; both for their child and for the family. This seemed to relate to the strive for normality and the question of what is normal; perhaps being able to respond to different demands in a flexible way.

*"...the biggest, advantage {yeah} em, for C1, probably, it makes it, you know, life is easier, she can have, well, do what she likes a wee bit more" (Parent 1, Lines 570-572)*

Often flexibility around meal times and around eating in general, were associated positively with the pump. Interestingly parents made use of the word 'freedom' in their accounts. Their descriptions of the pump enabling such a concept felt very powerful.



*"...it kinda gives him more options {yeah} when he can eat, and what he can eat {mm hmm} so it gives him that freedom as well" (Parent 3, Lines 109-111)*

*"I think all these things, which the pump, totally takes away {mm hmm} because, you now have the freedom to delay the meal, until she comes in after playing, or something like that {yeah} so it just gives her a lot more freedom." (Parent 4, Lines 130-138)*

This parent spoke directly about enablement, and how he felt that the pump was an aid for his child in moving forward with diabetes. This parent seemed to suggest that the practical ways that the pump helped his child, in turn helped her to move forward.

*"I think she feels, that um, the pump enables her [pause] rather, its not, its not holding her back, its not a treatment as such, it is a help [pause] rather than anything else, it actually allows her to do things and it allows her to manage things easier" (Parent 4, Lines 505-508)*

He went on to give a very frank opinion about the medical benefits of the pump in comparison to injections. This seemed to relate back to the idea of 'getting it right'; that somehow the pump gets it right, or perhaps enables them to get it right, or both.

*"...in terms of physical health [pause] obviously the pump, if used appropriately [pause] will actually give better outcomes than multi dose injections, cos, with the*

*best will in the world you cannot achieve the same, control with the injections as you can with the pump” (Parent 4, Lines 540-544)*

#### **3.5.2.4.2 Psychological Enablement**

Parents had given accounts of the emotional or psychological effect that diabetes had on their child. There seemed to be a strong feeling from parents that the pump helped their children to battle these difficulties. This seemed to resonate with the previous sub themes of ‘a new normal’; and that somehow the pump enabled them to consider and accept the idea of ‘a new normal’.

*“...she had been feeling, not right, for a long time, but just thought that’s the way, she was supposed to feel, because she wasn’t aware there was an option to feel better, then she got the pump [pause] her levels started to come down a wee bit, that she started feeling more energetic, and, and just happier in herself” (Parent 1, Lines 503-507)*

*“...but in terms of lifestyle, and her psychological well-being {mm hmm}, it’s a huge difference, that she, she’s just so much happier with the pump” (Parent 4, Lines 464-466)*

There was a feeling that the pump enhanced confidence and feeling safe in children, which allowed them to function in a healthy and happy way.

*“Em, and I think she feels as well... [pause] she knows that the pumps helping her to control her sugars [pause] more constantly {mm hmm} and better, so [pause] it has a knock on effect that she feels that the pump, will help keep her well” (Parent 2, Lines 484-489)*

This parent spoke about how the pump directly affected his child emotionally, and the knock on effect that had for his whole family.

*“Heavenly...and the whole thing was more because of her emotional change {ok} because she was so happy [pause] and she was so much better you know it just meant everything was so much easier {mm hmm} um, and just, reduced the load on the whole family, and the stress levels for the whole family as well” (Parent 4, Lines 385-390)*

This father spoke about the idea of acceptance, and how the pump seemed to enable psychological acceptance in his daughter. This parent had very strong views about how acceptance of diabetes was key for any child to be able to move forward and live a healthy and happy life with diabetes.

*“...you know dealing with the whole diabetes issue itself became so much easier {mm hmm} because em [pause] because of the change in attitude that (child’s*

*name) had [pause] and I think it also made her [pause] a lot more accepting of the fact that she's got diabetes, because she got the pump" (Parent 4, Lines 425-429)*

*"...its enabled her to accept the fact that she's got diabetes, um, because its made it less of an issue" (Parent 4, Lines 437-438)*

*"...however psychologically wise, and accepting her illness, and managing it in a logical and timely fashion, has become greatly better [pause] markedly better, since she's been on a pump." (Parent 4, Lines 604-607)*

There was a real sense that parents carried a lot of anxiety in relation to their child's diabetes. The idea of flexibility and convenience seemed to reduce parental worries, as of course did their feeling that their child was happier and healthier. The pump therefore seemed to enable parents to feel more confident towards their child's diabetes. This idea holds similarities to the previous theme of 'getting it right'.

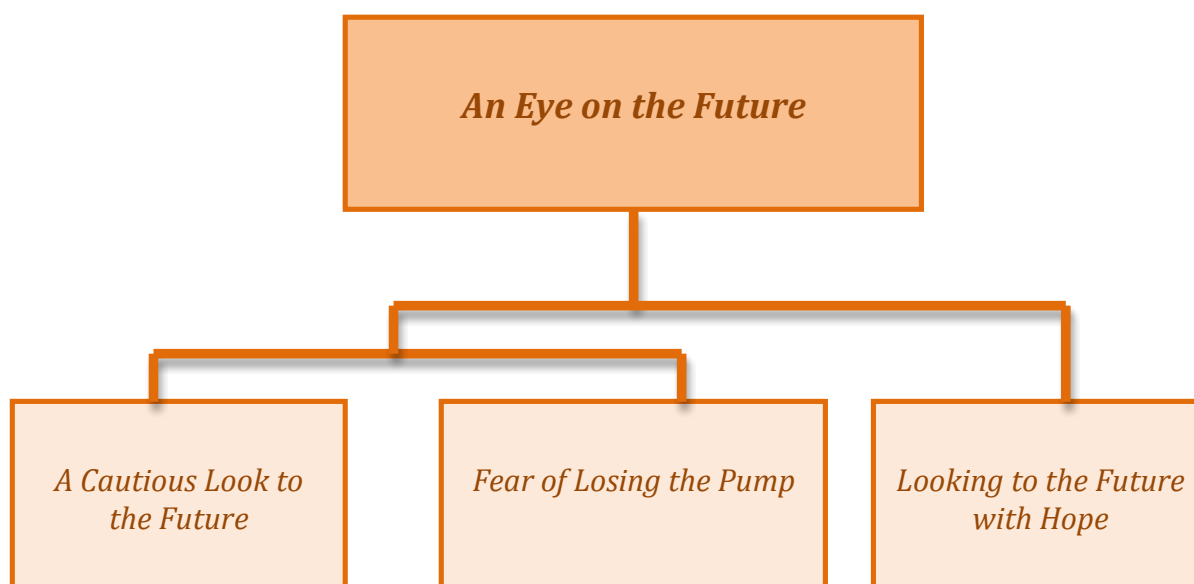
*"because we're less worried about it and, she's happier about her levels, and she's obviously feeling better it's just working all round, that everybody's, everybody's feeling better about it" (Parent 1, Lines 685-687)*

*"...not having for us, who is she away with, is she away with a friend, is she away with a friend who knows what happens when she has to inject, all those worries are no longer there." (Parent 2, Lines 40-42)*

### 3.5.2.5 An Eye on the Future

The final super-ordinate theme to emerge from the parent interviews was related to the future. All parents seemed to have ‘an eye on the future’, either in a positive hopeful way or in a more cautious way.

**Figure 3.6 Subthemes associated with ‘An Eye on the Future’**



#### *3.5.2.5.1 A cautious look to the future*

Parents looked to the future with caution. Some of this caution seemed to be based on their personal experiences with their child’s diabetes. There were underlying similarities to the previous theme of ‘expectations vs. reality’. It seemed that parents

had very direct experience of the ways in which expectations are not always met by reality; and therefore when looking to the future it made sense to be cautious.

This parent reflected on her child's duration of diabetes. She spoke about her worry for the future in the past tense, suggesting outwardly that the pump seemed to have reduced that worry. However there was still a feeling that diabetes was more powerful than the pump and despite being reduced by the pump, the worry about the future associated with her child's health would always be around.

*"...a big worry, was, for the long term, that [pause] and, you know, originally, our feelings were you know, when she was kind of, old in inverted commas, in her fifties maybe, but, you know when you, realise that, that, she's only twelve now and she's already had, she's twelve and a half, she's had diabetes for twelve years already, that's a long time, to have had [pause] to have had diabetes" (Parent 1, Lines 594-599)*

This mother looked forward to when her son would go to High School. She had specific worries about the details of this transition, which felt like they generalised to her overall worries about the future for her son in general. The use of the words 'terrified' and 'scared' demonstrated how powerful her fears about this were.

*"I'm just terrified when he goes to high school...There's no, there's nobody to look out for him really. There's not like an individual that'll prompt him or help him, and*

*it's a big transition from primary [pause] to high school. It's just an all of a sudden [pause] big huge jump {aye} its like from all to nothing, you know, from from uh huh, all or nothing kinda scenario {yeah} I'm scared of that"* (Parent 3, Lines 430–445)

This parent went on to look to the future in a slightly pessimistic way. She spoke about some of the difficulties that her son had experienced with diabetes earlier in his life. This account felt tinged with sadness associated with her son's experiences but positivity in relation to the future for other children with the insulin pump.

*"...well the damage is kinda been done with him because he was fluctuating so much, so, so he has problems with his emotions now [pause] but I think em, someone starting off [pause] going straight onto a pump would be better because they don't have these big huge rampant highs or [pause] or lows and going from one extreme to another within an hour [pause] em, I think it, it'd be far better for the child, not having this"* (Parent 3, Lines 706-712)

Parents looked to the future based on other people's experiences. This parent spoke about an encounter with someone else with diabetes.

*"Dad met a girl, a young, young girl who'd, lost her sight, in her twenties, because she'd, not kept her diabetes under control when she was younger so, all those kinda things happened around about the same time so it was all, more fuel for our*

*argument, that, you know, everybody needs to be on top of this, but, we, need to take more responsibility, she's still only twelve [pause] em, and we need to, to help her"* (Parent 1, Lines 224-229)

This mother looked forward to the future, and reflected on her personal experience of her sister who died from diabetes related complications. This experience certainly affected the way she viewed her son's future. However although she looked to the future with caution due to her insight, she also remained positive about her son's future. It felt as though the insight she had gained through her personal experiences equipped her to be able to look forward with her son in a functional way.

*"...so, I don't like him being high, I know how damaging it can be in the long term, um [pause] but [pause] you try not to, you know, convey your fears,"* (Parent 5, Lines 687-689).

*"I'm worried that he'll, you know, feel self conscious, and, you know, worried about it, when he's older and, see my sister, when she was a teenager she stopped taking her insulin, and that's, you know, was a big contributing factor to her, you know, her kidneys packing in, and, her glycoma and all the various other things"* (Parent 5, Lines 768-772)

#### ***3.5.2.5.2 Fear of Losing the Pump***



There was a feeling of pressure from parents, an idea that in order to have the pump, they have to achieve good glycaemic control, as though that is the sole function of the pump. One parent talked about justification for having the pump, which highlighted how sought after it was. There were feelings of 'getting it right' in these accounts that relate to previous themes.

This mother reflected on a particular time when her child's glycaemic control had deteriorated while she was on the pump.

*"the consultant was not happy [pause] because, you know, there was, there didn't seem to be any, any great advantage, its obviously more convenient for her, but, her levels weren't good, and they said, there was no point in her having the pump, if it wasn't gonna help to improve her levels [pause] em, but, I, I think we all kind of took a step back and said we need to sort of reassess, and, get on top of what she's doing"*  
(Parent 1, Lines 181-186)

*"...you know, it's a long way away from, actually taking the pump away from her, but he, was saying he would, when she got up to the next clinic he was gonna have to justify the expense, and if her levels were no better, then he wasn't wouldn't be able to justify, and eh, I think, that, that was something that, you know, we obviously knew that as, as adults but [pause] trying to get that across to her as well, that was quite hard [pause] em [pause] you know she doesn't know how much it*

*costs or anything like that, and that's, for her that's really not important at the moment"* (Parent 1, Lines 207-216)

This parent looked forward to the future and talked about her fear of losing the pump. This seemed to relate to the earlier themes of 'coping with uncertainty' and 'feeling powerless'.

*"My worry is if she goes into adolescence, that it would ever be taken off her, I cant see it ever happen because [pause] I think she, she would be soul destroyed for it to be taken off her"* (Parent 2, Lines 467-469)

The use of language such as 'soul destroying' and 'lost' in these parents accounts emphasises the meaning they think they pump has for their child.

*"I would hate the thought of her goin back and she would, I think it would just [laughs] it would be soul destroying for her to take it away from her"* (Parent 2, Lines 227-229)

*"I think, he'd be lost without this pump now, {right} I think he'd be lost without it."* (Parent 3, Lines 674-675)

This parent's worry about losing the pump was more in relation to her son choosing to have it taken away. She talked about her worries about it being on display. This seemed

to tie into the super-ordinate theme of 'strive for normality'; particularly in relation to 'the same but different' and feeling that in some ways, the pump enhanced the feelings of being different.

*"I'm sort of now thinking, when he's a teenager, I'm sort of slightly worried that he might have an issue with the pump, being so on display"* (Parent 5, Lines 103-105)

### *3.5.2.5.3 Looking to the future with hope*

All parents' accounts felt hopeful in many ways. Although several parents looked to the future in a more cautious way, even some of the caution felt positive.

There were several examples of parents looking forward to the future in terms of medical advances related to the pump or to diabetes treatment more generally.

*"I'm just looking forward to they start making more advances on the pump {uh huh} em [pause] cos you keep thinking there must be other things out there as well that they can do to control blood sugars [pause] em, d'you know, like continuous monitoring"* (Parent 2, Lines 471-474)

*"I think its great thing, I think its, it's the way forward, all this new technology, its just gonna get more and more advanced, cos its came such a long way"* (Parent 3, Lines 649-651)

*"The pump, its probably gonna be something far more advanced, by then {laughs}, I think it'll just, its gonna be something far better by then, I think its only just gonna get better and better and better {yeah} so I think this is like the first big stage and then there's gonna be, cos I think there's artificial pancreases and, whatever as well, there's a couple per year rolled out or something like that, I think there's, its gonna be the way forward" (Parent 3, Lines 658-663)*

*"it would be also great if they could, develop, you know, a pump that was also a sensor as well, so that you know, some kind of alarm or something could tell him when he was going low, um, but I would like that within the insulin pump" (Parent 5, Lines 749-751)*

This mother spoke about other advances towards diabetes treatment such as continuous monitoring with sensors. She refers to her sons future and talked about 'opportunities'. This felt similar to the previous themes associated with enablement. This mother seemed to look forward to the future at the advances in technology associated with diabetes treatment as having the potential to further enable her son.

*"I just think that's amazing thing I don't know, why they don't give them out. I know its another canula, that's the only down side, be another cannula, but [pause] I think, it'd give him better opportunities" (Parent 3, Lines 554-557)*

This father spoke about his hopes for the future being associated with his daughter's ability to cope with her diabetes and manage it. The pump featured in his future view.

*"I think once she's a wee bit older and she's got a bit more insight [pause] she will be able to control her sugar a lot better with the pump [pause] and um, the motivation will be there [pause] to maintain it within normal levels"* (Parent 4, Lines 544-547)

This mother acknowledged her son's role in his future with the pump, and made reference to the fact that he will decide his future with the pump.

*"Well I hope he sticks with the pump, but I hope, I hope the pump becomes more discreet in some way, for the kids, cos I think it is, a big issue for them, when they're so self conscious"* (Parent 5, Lines 746-748)

This father shared some very strong opinions about his views on wider systemic issues associated with the pump. This seemed to relate to the previous themes associated with enablement, but on a much wider scale.

*"we have a chance now, we can intervene now, if we do things now, by the time they get to twenty and they become, more aware, and they can control their sugar better, they don't have all the side effects, they will be normally contributing"*

*members of society, going out to work, having families, without any of the side effects or problems associated with their diabetes” (Parent 4, Lines 570-575)*

**Table 3.5 Distribution of super-ordinate themes and sub-ordinate themes across sample**

<b>Super-Ordinate Themes</b>	<b>Sub-Ordinate Themes</b>	<b>P1</b>	<b>P2</b>	<b>P3</b>	<b>P4</b>	<b>P5</b>
<i>Parenting a child with Diabetes</i>	Feeling Powerless		✓	✓	✓	✓
	Coping with Uncertainty	✓		✓		✓
	Getting it Right	✓	✓		✓	✓
	Other People Don't Understand			✓		✓
<i>Worth the Hard Work</i>	Expectations vs. Reality	✓	✓	✓	✓	✓
	Hard Work	✓		✓		✓
	Just Press a Button	✓	✓	✓	✓	
	Sticking With It	✓	✓	✓	✓	✓
<i>Strive for Normality</i>	The Same but Different	✓		✓	✓	✓
	A New Normal	✓	✓	✓	✓	✓
<i>The Pump as an Enabler</i>	Practical Enablement	✓	✓	✓	✓	✓
	Psychological Enablement	✓	✓		✓	
<i>An Eye on the Future</i>	A Cautious Look to the Future	✓	✓	✓		✓
	Fear of Losing the Pump	✓	✓	✓		✓
	Looking to the Future with hope	✓	✓	✓	✓	✓

## **3.6 REFLECTIONS**

### **3.6.1 Researcher's Reflections**

It is recommended that within IPA, researchers should clearly reflect upon their position within the research process (Smith *et al*, 2009). Quality assurance measures (Yardley, 2000) were followed closely by keeping an audit-trail of analytical decision making, and by the lead author maintaining a reflective diary. This ensured transparency of the researchers assumptions, experiences, prior knowledge and beliefs; including reflections on and reactions to interviews, transcription and analysis.

The following section is written in the first person and is illustrated with extracts from the reflective diary, in an attempt to capture the personal reflections of the researcher.

In the early stages of the study, I felt fairly confident. Although I had limited experience of conducting qualitative research, and certainly had never used IPA before; I had lots of experience talking to parents and children. I tried to view the first stage of my study as just that, and although I was researching the IPA approach, I tried to keep an open mind and take one step at a time. The first family I interviewed seemed to be very open and honest and engaged very well with me, although I quickly became very aware of how easy it would be to move towards a clinical interview, as opposed to a research interview. I was very conscious of the need to distance myself from questions that may be leading, which was particularly

difficult in the child interview. The following diary extract details my thoughts following the first two interviews.

*"...first family...Done! Went well...I think! Couldn't help thinking about it the whole way home, and wondering if I should have followed up certain questions with more prompts. I'm scared that the information will be useless. But I really got a feeling of how this family are experiencing things...I hope that doesn't mean I'm making hypotheses...I'm trying not to!"*

Despite some doubts following the first interviews, I remained confident in my ability. I had a good feeling about the information that the family shared with me and I felt that I had used my interview schedule appropriately and flexibly. I had enjoyed the process, and continued to enjoy the next two interviews. I was noticing distinct differences between the parent and child interviews (as I would have expected). I found a balance between directing the interviews and allowing participants to discuss the experiences that felt important to them; this balance was different for children than for parents. However, I hit a slight roadblock when I interviewed my third family. The child was much more difficult to engage and I became very aware of the difference between his interview and the previous ones.

*"Oh dear, I can't help wishing I could re-do that interview. Although I don't really think it was anything to do with me....? But I'm not sure if I've got any information that I can use...although I've obviously got what they wanted to tell me and what's important to them...surely that's the point? Starting to worry about analysis already!"*



I found myself dreading the transcription; but once I got started I enjoyed the process. I began to feel more reassured about the amount of information I had gathered; and in some cases I felt overwhelmed by it.

*“Actually enjoying the transcription process....didn’t think I would. Feeling a bit happier about the data I have got...especially from some of the interviews that I thought were too short. Some of the parent interviews feel huge! It’s taking a long time but I’m enjoying it. I think that’s because I don’t feel that I can get this bit wrong...it feels safe! Need to think more about that!!!”*

After I had completed my transcription I felt more comfortable about my sample size and about the data, but I started to feel apprehensive about how to analyse it.

*“Feel a sense of achievement from the ten neatly piled and typed transcripts sitting on my desk....but now thinking what do I do with them?! Got my coloured pens and my IPA book sitting at the ready...need to start!”*

After I completed my first analysis I reflected on how it had gone. I was worried that I might overlook key experiences. I started to question whether my clinical experiences from my training (that facilitated my initial confidence) would now unconsciously affect my interpretation of the data. I used peer support and supervision to talk over my concerns and found them very helpful

*“I found that hard! Was constantly second-guessing myself and thinking I was doing it wrong. However, once I’d done the reading and re-reading and got past the initial stages, I felt it starting to come together. Actually enjoyed pulling out themes. Supervision and discussion with colleagues was so helpful...”*

As Yardley (2008) recommends, I acknowledged my position as the principal researcher and thought about my personal and professional experiences may have impacted on the research process as a whole, but particularly on the analysis. I was very conscious of the impact that my role as a trainee clinical psychologist could have on the families' experience of my study. Although my role as researcher was clearly explained to them, I still worried about their interpretation of the whole thing.

*"I'm very aware of the fact that the families know I'm a trainee clinical psychologist, and yet they may never have seen a psychologist before. They are used to engaging with people in a medical setting in relation to the diabetes...worried what they may read into this..."*

In my reflective diary, I made reference to the fact that on a personal level I do not have a chronic illness; nor do I have any children. I was partly worried that parents would think I couldn't possibly understand, but I also worried that I may overlook key experiences. I was also very aware of the way my feelings about the whole process were changeable throughout.

*"Noticing that there is a great deal of ambivalence within the child accounts. I'm finding myself feeling ambivalent about things. I have worked with so many people (both adults and children) who have diabetes...but I don't have diabetes. Can I really understand these experiences? I feel like I do though...."*

Overall, I think that the research process highlighted my anxiety about getting things right. It was a steep learning curve, but one which has been invaluable. The process allowed me to gain confidence in the qualitative approach. On a personal level it allowed me the opportunity to be exposed to uncomfortable feelings of uncertainty

and to learn to sit with these feelings. I reached a point where I was able to acknowledge that the complexity of the process only reflected the complexity of people's experiences; and I was grateful to have been allowed some insight into them.

### **3.6.2 Participant's Reflections**

At the end of the interviews, participants were asked to reflect on their experiences of the interview process. Participants seemed to feel that the experience had been positive and allowed them to fully discuss their experiences.

*"Oh yeah, I just hope its some use to you...No it's good, good, anything we can do to help, or, and its good for us to speak to somebody about this..." (Parent 1, Lines 921, 925)*

*"I didn't really, I didn't know what type of questions you would ask, so I was kinda, thought of all different [laughs] possible answers like [pause] how its made a difference to me..." (Child 2, Lines 912-914)*

Following completion of the data analysis, the researcher sought respondent feedback by contacting two families (randomly selected). The emergent themes were discussed with the participants. All participants expressed a level of agreement with the themes during the discussion. Variation in levels of agreement across themes was related to the spread of themes present across cases. It should be acknowledged that this only represented a sub-section of the participants and that the agreement may not represent the entire sample as a whole. Furthermore, perceived 'power differentials' could have impacted on the participants' capacity to 'disagree' with the findings.

## **3.7 DISCUSSION**

This chapter will begin with a general summary of the current study. Although the same interview schedule was used for both parents and children, the analysis indicated quite different results. Following a section considering reflections on the parent interviews, there will be a general discussion, which will incorporate reflections from the child interviews (discussed in detail in section 3.4.6) and will look broadly at the complete data set. A methodological critique will be presented, including both strengths and limitations. Finally the clinical implications and recommendations for future research will be discussed.

### **3.7.1 General Summary of Results**

The aim of this study was to explore the experiences of children who use an insulin pump, and that of their parents.

Ten participants took part in the current study (five children and five parents). The age of the children (three females and one male) ranged from 9 to 12 years. Four mothers and one father participated in the parent interviews. All participants were recruited via the pediatric diabetes clinic and were identified by the pediatrician.

The current study employed a qualitative methodology using IPA (Smith, 1996; Smith *et al.*, 2009) as the method of analysis. Data was collected via the use of semi-structured interviews and transcribed by the researcher verbatim. Child and parent interviews were analysed separately in order to give a full account of each groups' experiences and avoid the risk of one group dominating over another. IPA has been used in a variety of ways to gain multiple perspectives such as looking separately at

child and parent data (Griffiths, 2009; Wilkinson, 2010) looking at directly related groups (Rostill, *et al.* 2011); families (Penny, *et al.* 2009; Dancyger, *et al.* 2010); indirectly related groups, (Larkin & Griffiths, 2004); dyads written as pairs, (Wane, *et al.* 2009; Clare, 2002; de Visser & McDonald 2007); and dyads written as groups, (Larkin, *et al.*, 2009). This study opted to consider the two sets of data separately, although reflections will be made on the complete data set in order to examine any wider themes throughout.

Analysis of the child interviews revealed three master themes: *'Feeling Different; 'Better...';* and *'Grappling for Control'*. These themes are discussed in more detail in section 3.4.6. Analysis of the parent interviews revealed five super-ordinate themes: *'Parenting a Child with Diabetes'; 'Worth the Hard Work'; 'Strive for Normality'; 'The Pump as an Enabler';* and *'An Eye on the Future'*.

### **3.7.2 Reflections on Parent Results**

#### **3.7.2.1 Parenting a child with diabetes**

Participant accounts had a huge focus on the experience of parenting a child with diabetes. There was a feeling from parents that parenting a child with diabetes, was a full-time job that impacted on the whole family, as may be the case with parenting any child, however the priority of the parents would often have to be the care of the child who has diabetes in order to comply with the acute nature of the regime. The idea of hard work emerged throughout this theme, as well as in later themes.

A number of studies have reported on the extreme stress that parents experienced in parenting a child with diabetes (Guthrie, 2003; Sullivan-Bolyai, 2004; Tamborlane *et al*, 2006). Specifically Hatton, *et al*. (1995) related it to the seriousness of the child's condition at the point of diagnosis, the pervasive nature of diabetes and their responsibility for managing their child's health in the long-term. These findings are comparable in many ways to the current study, specifically in relation to the parents' responsibility and feelings of pressure to 'get it right'. These feelings resonated throughout the parent accounts, regardless of the perceived benefits of the insulin pump, suggesting that diabetes is the source of anxiety. Alsaleh *et al* (2012) reviewed a number of qualitative studies and found that reported parental involvement and levels of anxiety did decrease following commencement of CSII, but not substantially.

Marshall *et al* (2009) showed that no matter what age the child is, parents needed to reassure themselves through checking up on their child, suggesting their own anxieties about their child's health and about their role in 'getting it right'. They suggested that parenting a child with diabetes was like a switch that could not be turned off. This 'hypervigilance' may be likely to cause increased tension and conflict as children approach adolescence. This may cause the children to feel different, which emerges as something that both parents and children are trying to avoid. It has been shown that parents experience a great deal of loss: loss of their previously healthy child, loss of their freedom and loss of their confidence (Marshall *et al*, 2009). This related to the findings in the current study that showed parents as feeling powerless. The powerlessness related to uncertainty and responsibility and ultimately suggested that parents were unable to feel confident in relation to

parenting their child; because diabetes was more powerful and unpredictable. Guthrie *et al.* (2003) refer to the inner conflict that parents experience in terms of the push-pull relationship they have with responsibility of their child's diabetes; and suggest that better treatment of diabetes in terms of improved glycemic control can facilitate a resolve to this conflict.

Marshall *et al* (2009) suggest that much of parents' ability to provide the necessary support to their child with diabetes comes from knowledge and understanding. This relates to the current study because the parents made reference to the fact that other people didn't understand; with particular reference being made to friends, family and school. Again, parents seemed to work very hard to gain this knowledge and understanding to improve their confidence in managing their child's condition; which links with the idea of 'hard work'. There was a real sense of parental responsibility for their child in the 'fight' with diabetes and the pump seemed to be viewed as a proxy for this – perhaps releasing some of the responsibility. Sartain *et al.* (2000) suggest that children are often perceived as passive in the sickness process, often based on a wish to protect their welfare. This idea would fit with the current study, as there was a sense of passivity of the child, which felt related to the parent's developing relationship with the pump. Parents' did not reflect much on their specific coping strategies, and perhaps the use of the pump was a coping strategy for them; or perhaps this was because there was no perception of choice for them, they had to cope. Again this ties in with feelings of powerlessness.

#### 3.7.2.2 Worth the Hard Work

The resounding view to come out of the parent interviews was that the insulin pump was worth the hard work. There was no question that it was hard work, but parents undoubtedly appreciated the benefits and attributed a great deal of worth to the pump, in line with previous findings (Wilson, *et al.* 2008). Sullivan-Bolyai *et al.* (2004) found that parents' overwhelmingly reported that the pump was a superior tool for managing their child's diabetes. This was related to achieving better glycemic control, and potentially fits with the idea of 'getting it right'. It also seems to fit with the idea that the pump was as an enabler.

There were references to the pump as some kind of 'saviour' or external solution to some of the problems that could be caused by diabetes and yet there was a feeling of a resulting disappointment when changes weren't as far reaching as expected; the goal of normality wasn't quite reached. This fitted with the sub theme of 'expectations vs. reality'. Sullivan-Bolyai *et al.* (2004) reflected on the parental expectations in their study; and the lengths that families would go to in a quest to receive CSII, highlighting that they had positive expectations for the pump. Insulin pumps seem to be very sought after (Wilson, *et al.* 2008; Sullivan Bolyai, *et al.* 2004). In relation to expectations, a study of adults with CSII (Ritholz *et al.* 2007) showed that active participation included an understanding that the pump was a tool to increase flexibility in life with diabetes but not a mechanism for complete freedom from diabetes. This study showed that the participants with poorer glycemic control expressed unrealistic expectations were more passive towards self-care and ultimately had poorer glycemic control as a result. There was an expectation of the pump as a 'miracle' that would allow them to do as they pleased. This finding regarding expectations of the pump is also reported in adolescents (Low, *et al.* 2005).



McMahon et al. (2004) found that families who take on the task of CSII are required to be highly motivated in relation to the increased demand of certain diabetes routines. There was a feeling that this perhaps was not as parents had expected before they got the pump, but that they were able to adapt to the hard work, partly to achieve improved outcomes; and partly in pursuit of their hopes for normality.

### 3.7.2.3 Strive for Normality

Achieving normality was something that seemed to be aspired to by families. The theme, 'strive for normality' encompassed the sub themes of 'same but different' and 'a new normal'. These themes fell into an almost temporal sequence. Families gave accounts of fighting a battle to achieve normality, which is likely to be an ongoing struggle throughout adolescence, and is likely to be fought alongside their child's fight to fit in and maintain a sense a self. There was a sense that living with diabetes changes what is 'normal' for families; and perhaps they have already reached a state of a 'new normal', as they adapt to life with diabetes and its routines. However the introduction of the pump might suggest that again the families need to reach a state of a 'new normal', perhaps reflecting on the resilience within the families and the ability to adapt to unexpected situations. This may be strengthened by the parents' exposure to uncertainty through general parenting of a child with diabetes, as shown in the previous theme.

This compelling need to normalise life has been found in several other studies of parents of children with chronic illnesses (Griffiths, 2009; Wilkinson, 2010) and was the central theme identified in a study exploring the perspectives of parents and

children with type 1 diabetes (Marshall, *et al*, 2009). There seems to be a constant strive to achieve a balance between trying to manage all the things that make their child different, whilst trying to treat them the same as everyone else.

There is also a well documented trend of decreasing diabetes adherence in the context of normal adolescent development; which is likely impact families strive for normality, when normal is to not adhere, or normal is to be different.

#### 3.7.2.4 The Pump as an Enabler

Parents seemed to view the pump as having the capacity to enable their child to manage diabetes and the psychological consequences of diabetes better. However, they were also aware that this enablement did not necessarily equate to building a perceived internal locus of control and certainly a theme was an increased external locus of control.

Low *et al.* (2005) reported that only a small number of parents in their study reported increased dependence following CSII suggesting that dependence decreased with the pump. This fits with the theme of 'the pump as an enabler', which suggested that parents felt that the pump allowed their child more flexibility and freedom. However it may be that the dependence or perceived external locus of control had shifted from the parent to the pump; hence the pump as an enabler. Sullivan-Bolyai (2004) reported that parents in their study noticed improvements in their child's mood with the pump. This was evident in the current study with parents making reference to their child as being happier and better equipped to manage the psychological demands of diabetes. They also reported improvements in flexibility within family

life, again in line with the idea of practical enablement in the current study and the notion of 'pressing a button'.

#### 3.7.2.5 An Eye on the Future

Hatton *et al* (1995) showed that some of the stress that parents of children with diabetes experience is related to the fact that they effectively have one eye on the future and are very aware of their responsibility in the long term care of their child. Having an eye on the future does not seem unusual as a potential feature of parenting; however some of the caution perceived in the parents future views felt directly related to diabetes. The hopeful views of the future were either related to ongoing medical advances in relation to diabetes management or in relation to passing responsibility to their child and worrying about that.

Marshall *et al* (2009) identified 'transition' as a theme, in relation to children's strive for independence and the tensions that exist between parents and children. Their study included adolescents up to the age of 17 years, who were likely to be moving closer to wards independence and taking responsibility. Despite the fact that the oldest child in the current study was 12 years old, parents still had their eye on the future and anticipated some of the tensions and battles that were likely to be in front of them.

It is interesting that parents reflected on uncomfortable feelings of pressure to get it right and feelings of powerlessness and uncertainty; given that the most frequently reported reason for selection of children for CSII is inadequate diabetes control (Fisher, 2006). Given then that many families will be on a path away from poor

diabetes control it is not surprising that they are hopeful about the future with the pump, while remaining cautious (given their previous experiences). The fear of losing the pump may therefore be tied in with the original selection procedures for receiving it in the first place, i.e. the fact that they will have been in a position of powerlessness, uncertainty and perceived as getting it wrong, perhaps coupled with parents knowledge about the cost.

#### **3.7.4 Overall Reflections – parents and children**

Although the same interview schedule was utilised for both parents and children, the analysis clearly indicated different resulting themes for both groups. Despite the differences found across the two data sets, there were also some similarities that ran through the two sets of results. In some ways the themes found in the parent data supported those found in the child data and vice versa. Analysing the data separately ensured that such intricate comparisons could be made, and that one group didn't dominate the other.

The children's theme of 'Feeling different', which considered the ways that the pump threatened and protected their identity, was mirrored in the parent them of 'A strive for normality', and some of the issues found within 'parenting a child with diabetes'. The children's theme of 'Grappling for control' considered the conflict between the child's internal and external locus of control. The development of an internal locus of control in the context of diabetes requires facilitation from parents and caregivers and although parents seemed to consider the pump as an enabler for their child, children seemed more literally to shift their locus of control from their parents to the pump, hence not being enabled as such. Both parents and children acknowledge the

effort required to make the pump work: the parents consider this as the meeting of their expectations versus the reality; children simply make the black and white comparisons between prior and current regime.

The idea of control tends to be central to diabetes research; and the feeling that diabetes is a 'balancing act'. This idea of balance reflected throughout almost every account, parent and child; and there seemed to be two sides to every theme. In line with previous research, the current study supports the idea that children are able to identify both advantages and disadvantages of the insulin pump (Olinder *et al*, 2007; Low *et al*, 2005). Of course there is a real need to achieve a balance when it comes to medical outcomes such as glycemic control. However, it seemed that for every theme, there was a balance to be found: The 'same but different'; 'better but not perfect'; 'expectations vs. reality'; 'hard work but worth it'; internal locus of control vs. external locus of control'. Perhaps balance or control is actually central to life with diabetes; and the pump is just another part of that. Children were less able to articulate this as a balance and therefore it felt like ambivalence; which may be the case, but perhaps this ambivalence can be transformed into a balanced view as the children grow up. A study exploring the lived experience of adolescents with diabetes found such conflict to be a central theme (Dickinson & O'Reilly, 2004).

The idea of normality featured in both parent and child interviews and seemed to be strongly associated with wanting to be perceived and treated the same as non-diabetics. For children there was a strive for normality which emerged more in terms of their feelings of being different; and a strive to fit in. Parents seemed to be very aware of this; and they too attempted to help their child fit in. Parents seemed

to be more aware of the idea of being the same but different; which translated into finding a 'new normal'. Children's accounts were perhaps more concrete and the seemed less able to acknowledge the idea of same but different. Children certainly seemed aware of feeling different, and were able to reflect on the ways in which the pump either exacerbated or helped with this uncomfortable feeling; however there was less reference to trying to achieve a new normal; and instead the accounts reflected either feeling different or fitting in.

Ritholz and colleagues (2007) examined locus of control in adults with diabetes using CSII and found that those adults that viewed the insulin pump as a tool to meet glycemic goals, evidenced a more active approach to diabetes and ultimately had better glycemic control. Those who viewed it more as a panacea described more passive self-care and ultimately had poorer glycemic control (Ritholz *et al.*, 2007). This resonates with the children and adults in the current study; who seem to be trying to find a balance with both of these ideas, in the strive to get it right. Similar results were found in a study of adolescents' perceptions of CSII (Low, *et al.* 2005).

Silverstein *et al* (2005) provides a useful account of the management priorities for children with diabetes and how these compare with normal developmental tasks at different ages and stages. According to their research, the children in the current study would therefore be trying to balance management priorities such as the integration of their diabetes regime into their life to allow for participation in school and peer activities; while learning about the short and long term benefits of optimal control. They suggest that these diabetes tasks have to be integrated with the normal developmental tasks such as consolidating self-esteem with respect to peers and

developing a sense of self-identity (Silverstein *et al*, 2005). Certainly these themes were strong in the current study and reflected perhaps within the parents 'eye on the future', in relation to their fears of letting go of some of these management tasks.

### **3.7.5 Methodological Critique**

#### **3.7.5.1 Strengths**

To the author's knowledge this is the first study in Scotland to explore children's experience of CSII. Furthermore it has been suggested that pre-adolescent children have been neglected in terms of research into their experiences of health conditions in general and managing it (Gannoni & Shute, 2009). This study therefore addressed this under researched group of children.

The fact that this study adopted a qualitative approach meant that an in-depth description of experiences, detailing complex accounts could be gathered. It seems unlikely that such complexities could have been explored through the use of quantitative measures alone; particularly given the measurement difficulties with related constructs such as QoL.

The researcher took a number of addition steps to enhance the methodological rigour of the study, including the utilization of a reflective diary, supervision, multiple reviewers to corroborate themes, respondent validation and the presentation of extracts and summaries to provide evidence of transparency (Yardley, 2000).

#### **3.7.5.2 Limitations**

The current study has a number of methodological limitations. The CSII population in Scotland and in the particular health board where the research was conducted, represents a very small percentage of people with type 1 diabetes. Perhaps a wider recruitment from other diabetes units may have allowed for a more representative sample. Furthermore, recruitment of participants was achieved with the assistance of the pediatrician, which could have resulted in a possible selection bias. Although the first five families who were approached by the pediatrician agreed to participate, suggesting that the families were keen to engage.

It may also be the case that the participant's accounts were influenced by the position held by the researcher. Despite a detailed participant information sheet and supplementary discussions, participants, particularly children, may have been reluctant to discuss negative aspects of their treatment because they perceived the researcher as another health care provider. However, despite this consideration, it seemed that the participants in fact gave very rich detailed descriptions encompassing both positive and negative views about their treatment.

Findings from this study, particularly in relation to the children's data may not be directly transferrable to other age groups given the different developmental requirements of different stages, and how these integrate with diabetes related requirements (Silverstein *et al*, 2005); however the findings are similar to previous research carried out in adolescents (Dickinson & O'Reilly, 2004).

Demographic information was not collected in this study and therefore certain factors were not considered such as the participant's socio-economic and cultural



background, which can have an effect on diabetes control and consequently other issues (Whittemore, 2003). Furthermore, this study did not control for co-morbid health conditions, which may be likely to impact on children and their parents. It also did not consider the different types of pump that are available (e.g. tethered or untethered), and the effect that this could have had on perception of flexibility etc. Use of sensors was also not considered, and although it was not raised, there is no guarantee that sensors and continuous monitoring devices were not being used in this sample, which has been shown to have an effect on participant's perception of benefit associated with CSII (Cemeroglu, *et al.* 2010; Glaser, *et al.* 2004).

### **3.7.6 Clinical Implications**

Based on the themes that emerged from the current study, in line with previous literature, there are a number of recommendations that can be made for clinical practice and service provision of children with diabetes using CSII (and their parents).

Children, particularly children with chronic illnesses cannot be treated as homogenous, and further application of qualitative research methods is necessary to continue to try to understand the experiences and diversities of childhood, chronic illness and how they interact at various developmental stages, and within a variety of systems (Sartain *et al.*, 2000).

The cost of CSII has not been considered in this study, although parents made reference to it as an expensive form of treatment. Evidence on the long term cost-effectiveness is limited at the moment (Eugster, 2006; Nuboer, *et al.* 2006; Mack-Fogg, *et al.* 2005), with very little research published looking at the cost effectiveness of CSII

in either adults or children (Phillip, *et al.* 2007). Given the paucity of research in this specific area, it is interesting that families had a strong feeling about the cost, which in some ways seemed to add pressure to them in relation to 'getting it right' and exacerbated their 'fear of losing the pump'. Perhaps it should not be overlooked for future research, particularly given the current economic climate.

Given the findings suggesting a struggle with expectations meeting reality, health care providers should assess patients' expectations of the pump, if only to try to dispel magical beliefs and unrealistic expectations (Silverstein *et al.*, 2005).

It has also been suggested that the ways in which health care professionals interact with children and adolescents with diabetes can ultimately have an affect on their diabetes management (Dickinson & O'Reilly, 2004); suggesting consultations should allow the children to participate in decision making to contribute to positive interactions and outcomes. These findings would fit with the current study, as the children try to resolve some of their ambivalence in relation to diabetes and their day to day developmental tasks. Involving children their own health care facilitates the acquisition of self care, decision making and self monitoring (Nicholas *et al.* 2010). However it is recognized that consultations are time limited and staff training and consultation may facilitate this and would be in line with National Recommendations (Scottish Government, 2010, NICE, 2008).

### **3.7.7 Possibilities for future Research**

Support for the current study's findings has been located within some of the existing literature and clinical implications have been indicated. However a number of additional areas and questions for further research have been highlighted.

Sullivan-Bolyai (2004) found that communication between parents improved with the pump; perhaps this merits further research, particularly given the stress that having a child with diabetes can put on a marriage (Guthrie *et al*, 2003). They involved fathers in their research, along with mothers, and found that the families viewed this as a joint management agreement. Given that the current study only interviewed one father, involving fathers in future research would be useful. It has also been shown that fathers can have a greater influence than mothers on some children's adjustment to having diabetes (Guthrie *et al*, 2003).

The children in the current study were in a limited age range, which was deliberate to keep the sample homogenous, however none of the participants were at a particularly transitional stage. Further research should address the experiences of children across different transitional stages; and how the pump fits each stage. This is certainly something that parents identified in their accounts when they looked towards the future. The locus of control concept was an interesting finding from this study, in light of previous research, that merits further examination. Given that locus of control changes across the developmental age range, it was interesting that the theme was present in all the children in this study (despite different ages). It would be interesting to look closely at locus of control associated with CSII in teenagers.

Research involving the voice of health care providers would be useful, since they manage the families' in what are often acute situations. Taylor *et al* (2010) refer to the complexity of pediatric interactions and suggest that they consist of a balance between each child, family, and illness. The results of their study indicated that clinicians should utilise patient-centered communication in pediatric consultations in order to adapt to the rapidly changing concept of childhood, suggesting that developmental considerations are not always accounted for in consultations (Taylor *et al.*, 2010). However they maintain that children's voices should be heard (Alderson *et al*, 2006). Focus groups with staff teams, or interviews with staff and families together may be likely to produce interesting results.

Carroll & Marrero (2006) reflected on the role of significant others in their study of adolescents with diabetes and concluded that providers should pay more attention to the important role that parent and child relationships play in acceptance and management of diabetes. Future research could explore the actual relationship between parents and children in relation to CSII, perhaps conducting joint interviews or focus groups.

Barnard and colleagues (2008) suggests that future research should consider the ways in which children and adolescents are selected for CSII and how their suitability is assessed. Plotnick *et al.* (2003) reported monitored frequency and parental involvement and showed a very close correlation with reduced HbA1c concluding that parental involvement was a predictor of success. It is suggested that in the adult population, more research is required to examine which people are most

able to meet the demands of CSII (Barnard *et al.* 2007); in the pediatric population this would mean working closely with parents capacity to manage such demands.

### **3.7.8 Conclusions**

The current study has attempted to provide a greater insight into the lived experience of children using CSII and that of their parents. The findings suggest that both children and their parents fight to develop a balanced relationship with diabetes. The insulin pump certainly helps in this quest; but there was a realization that it wasn't perfect and took a lot of effort, particularly in the parents' behalf. Findings suggest that children have an ambivalent relationship with diabetes and therefore with the insulin pump, although this relationship seemed to be one that was developing and had the potential to become more functional. Certainly the relationship that children were developing with the pump had an effect on their perceived locus of control and on their self identity, particularly with peers. Parents seemed to carry most of the burden of their child's diabetes in their attempt to get things 'right' and overcome the feelings of powerlessness and uncertainty that come with parenting a child with diabetes. The child therefore seemed to have more of a passive role, which could potentially have contributed to some of the ambivalence that emerged in the accounts of the children, ambivalence which perhaps exacerbated the parents' cautious look to the future.

It is hoped that these findings may be of particular interest to health and social care professionals involved in with children with diabetes. Specifically it should be acknowledged that diabetes continues to be hard work, despite the perception and evidence of improved glycemic control with the insulin pump.

The dissemination of these findings will contribute to the small evidence base into CSII in pediatrics, which not only provides the professionals that work with these children more insight into the lived experiences of this group, but also emphasises the ongoing importance of carrying out research from an insider perspective.

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## APPENDIX 1

### Quality Assessment Rating Tool

## Appendix 1: Quality Criteria Assessment Sheet

Quality Criteria Assessment Sheet		
Author:		
Title:		
Year of Publication:		
Study Design:		
Checklist completed by:		
SECTION 1: RATIONALE		
1.1	Is the hypothesis/aim/objective of the study clearly described?	Yes = 1 No = 0
1.2	Does the study address an appropriate and clearly focused question? (i.e. is there a clear link between the rationale and the method proposed)	Yes = 2 Partially = 1 No = 0
TOTAL: SECTION 1		/3
SECTION 2: PARTICIPANTS		
2.1	Has the population, and how it was identified and recruited been clearly stated?	Yes = 2 Partially = 1 No = 0
2.2	Are the characteristics of the participants included in the study clearly described?	Yes = 2 Partially = 1 No = 0
2.3	Were the participants recruited from the same population?	Yes = 1 No/Not Stated = 0
2.4	Were the participants recruited over the same period?	Yes = 1 No/Not stated = 0
2.5	Are the distributions of principal confounders in each group of subjects clearly described? (e.g. other health probs, socioeconomic factors etc)	Yes = 2 Partially = 1 No = 0
TOTAL: SECTION 2		/8
SECTION 3: DESIGN/METHOD		
3.1	Are the inclusion/exclusion criteria clearly stated?	Yes = 1 No = 0



3.2	Are the inclusion/exclusion criteria appropriate to test the hypothesis?	Yes = 1 No/not stated = 0
3.3	Is the sample size stated?	Yes = 1 No = 0
3.4	Does the study have a control group?	Yes = 1 No = 0
3.5	Has the assignment of participants to groups been randomized?	Yes = 1 No/not stated = 0
3.6	Have appropriate methods been used to implement the random allocation sequence?	Yes = 1 No/not stated = 0
3.7	Has an adequate concealment method been used?	Yes = 1 No/not stated = 0
3.8	Is there a clear explanation/justification for assessment criteria and measures used?	Yes = 2 Partially = 1 No = 0
3.9	Are all relevant outcomes measured in a standard, valid and reliable way for use with the sample population in relation to the focus of the study?	Yes = 2 Partially = 1 No = 0
3.10	Are losses of patients to follow-up taken into account?	Yes = 1 No = 0
TOTAL: SECTION 3		/12
SECTION 4: RESULTS/STATISTICAL ANALYSIS		
4.1	Are the results clearly reported?	Yes = 2 Partially = 1 No = 0
4.2	Is the analysis appropriate to the study design and outcome measure used?	Yes = 2 Partially = 1 No = 0
4.3	Have confidence intervals, effect sizes, p-values etc been provided where appropriate?	Yes = 2 Partially = 1 No = 0
TOTAL: SECTION 4		/6
SECTION 5: DISCUSSION/CONCLUSIONS		
5.1	Are the results appropriately interpreted taking into account study hypotheses and limitations?	Yes = 2 Partially = 1 No = 0
5.2	Is the generalisability of the findings discussed?	Yes = 2 Partially = 1 No = 0
5.3	Are recommendations for clinical practice or future research discussed in relation to findings?	Yes = 2 Partially = 1 No = 0
TOTAL: SECTION 5		/6

## QUALITY SCORE

OVERALL TOTAL: \_\_\_\_/35

PERCENTAGE: \_\_\_\_%

QUALITY RATING:    A HIGH QUALITY (>75%)            ☐  
                              B MODERATE QUALITY (50-74%)       ☐  
                              C POOR QUALITY (0 – 49%)                ☐

RATER COMMENTS/NOTES:

## APPENDIX 2

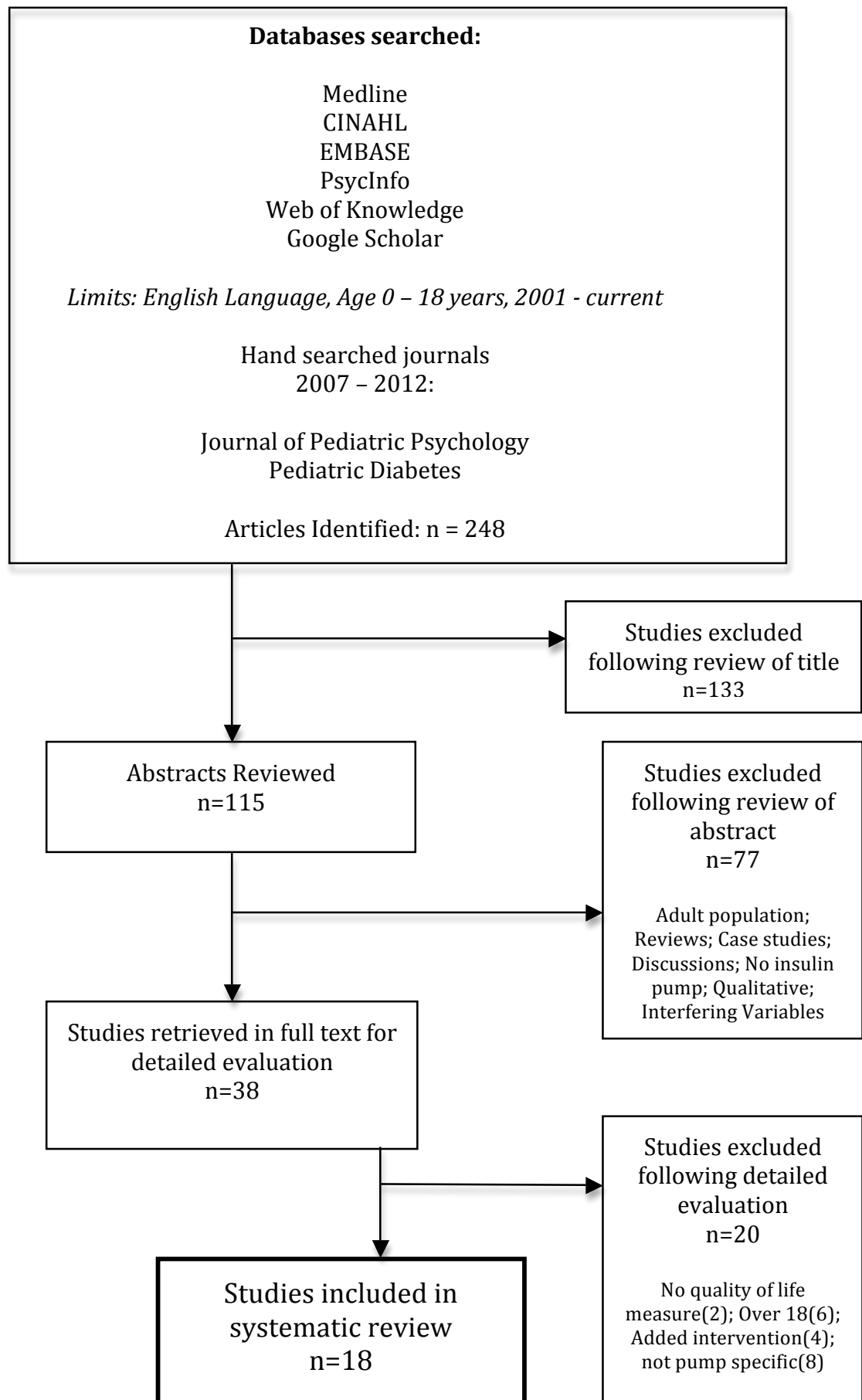
### Table of Quality Ratings

	<b>Quality Criteria</b>					<b>Total Score</b>	<b>%</b>	<b>Overall Quality Rating</b>
	(1)	(2)	(3)	(4)	(5)			
<b>Studies</b>								
1. Barczykowska <i>et al.</i> (2011)	3	3	7	3	3	19	54%	Moderate
2. Wu <i>et al.</i> (2010)	3	6	6	4	3	22	63%	Moderate
3. Hilliard <i>et al.</i> (2008)	3	6	7	5	6	27	77%	High
4. Muller-Godeffroy <i>et al.</i> (2009)	2	5	8	6	6	27	77%	High
5. Nuboer <i>et al.</i> (2008)	3	8	10	5	3	29	83%	High
6. Johannesen <i>et al.</i> (2008)	3	6	5	3	4	21	60%	Moderate
7. Kawamura <i>et al.</i> (2008)	2	6	6	2	3	19	54%	Moderate
8. Opiari-Arrigan <i>et al.</i> (2007)	2	5	8	5	5	25	71%	Moderate
9. Cogen <i>et al.</i> (2007)	2	5	3	3	3	16	46%	Poor
10. Juliusson <i>et al.</i> (2006)	2	6	5	5	5	23	66%	Moderate
11. Valenzuela <i>et al.</i> (2006)	3	8	8	5	6	30	86%	High
12. Fox <i>et al.</i> (2005)	3	6	7	5	6	27	77%	High
13. Wilson <i>et al.</i> (2005)	3	5	12	4	6	30	86%	High
14. O'Neil <i>et al.</i> (2005)	3	8	5	5	6	27	77%	High
15. Mednick <i>et al.</i> (2004)	3	6	5	3	6	23	66%	Moderate
16. Shehadeh <i>et al.</i> (2004)	2	4	5	4	3	18	51%	Moderate
17. Weintrob <i>et al.</i> (2003)	3	6	8	4	4	25	71%	Moderate
18. Cohen <i>et al.</i> (2003)	1	0	8	3	3	15	43%	Poor

1 = Rationale 2 = Participants 3 = Design/Method 4 = Results/Statistical Analysis 5 = Discussion/Conclusion	>75% = High Quality 50 – 74% = Moderate <50% = Poor Quality
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## APPENDIX 3

### Systematic Review Search Pathway



## APPENDIX 4

### Letter of NHS Ethics Approval

**West of Scotland REC 5**  
Ground Floor - Tennent Building  
Western Infirmary  
38 Church Street  
Glasgow  
G11 6NT

Ms Lesley A Allan  
Trainee Clinical Psychologist  
NHS Forth Valley  
Adult Clinical Psychology, Old Nurse's Home  
Falkirk Community Hospital  
Major's Loan  
Falkirk  
FK1 5QE

Date 03 February 2012

Direct line 0141 211 2102  
Fax 0141 211 1847  
E-mail [sharon.macgregor@ggc.scot.nhs.uk](mailto:sharon.macgregor@ggc.scot.nhs.uk)

Dear Ms Allan

**Study title:** Insulin Pump Use in children with type 1 diabetes: An exploration of families' experiences  
**REC reference:** 11/WS/0129

Thank you for your letter of 16 January 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

#### **Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

#### **Ethical review of research sites**

##### **NHS sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### **Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

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[v.nhsggc.org.uk](http://v.nhsggc.org.uk)



Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations*

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

### **Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Interview Schedules/Topic Guides	1.0	01 December 2011
Investigator CV		28 November 2011
Other: Consent to Contact Form	1.0	28 November 2011
Other: Child Assent Form	1.0	28 November 2011
Other: Supervisor's CV		26 August 2011
Participant Consent Form: Parent	1.1	09 January 2012
Participant Consent Form: Child	1.0	09 January 2012
Participant Information Sheet: Younger Child	1.0	09 January 2012
Participant Information Sheet: Parent	1.1	09 January 2012
Participant Information Sheet: Older Child	1.1	09 January 2012
Protocol	1.0	28 November 2011
REC application		28 November 2011
Response to Request for Further Information		16 January 2012

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### **After ethical review**

#### Reporting requirements

The attached document "*After ethical review – guidance for researchers*" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study



The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

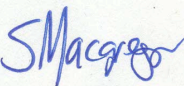
Further information is available at National Research Ethics Service website > After Review

**11/WS/0129**

**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

  
Dr Gregory Ofili  
Chair

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Marise Bucukoglu, University of Edinburgh  
Dr Allyson Bailey, NHS Forth Valley

## APPENDIX 5

### Letter of NHS Management Approval

Date: 12 March 2012

Your Ref:

Our Ref:

Direct Line: 01324 677564

Email: [allyson.bailey@nhs.net](mailto:allyson.bailey@nhs.net)

R&D ref: FV648

Ms Lesley A. Allan  
Trainee Clinical Psychologist  
NHS Forth Valley  
Adult Clinical Psychology, Old Nurse's Home  
Falkirk Community Hospital Major's Loan  
Falkirk  
FK1 5QE

Dear Ms Allan

**Study title: Insulin pump use in children with type 1 diabetes: an exploration of families experiences**

**NRES number: 11/WS/0129**

Following the favourable opinion from the West of Scotland REC 5 Research Ethics Committee on 03 February 2012, I am pleased to confirm that I formally gave Management Approval to the study above on 12 March 2012.

This approval is granted subject to your compliance with the following:

1. Any amendments to the protocol or research team must have Ethics Committee and R&D approval (as well as approval from any other relevant regulatory organisation) before they can be implemented. Please ensure that the R&D Office and (where appropriate) NRS are informed of any amendments as soon as you become aware of them.
2. You and any local Principal Investigator are responsible for ensuring that all members of the research team have the appropriate experience and training, including GCP training if required.
3. All those involved in the project will be required to work within accepted guidelines of health and safety and data protection principles, any other relevant statutory legislation, the Research Governance Framework for Health and Community Care and IHC-GCP guidelines. A copy of the Framework can be accessed via the Chief Scientist Office website at: <http://www.cso.scot.nhs.uk/Publications/ResGov/Framework/RGFEdTwo.pdf> and ICH-GCP guidelines may be found at <http://www.ich.org/LOB/media/MEDIA482.pdf>
4. As custodian of the information collected during this project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT security policies, until the destruction of this data.
5. You or the local Principal Investigator will be required to provide the following reports and information during the course of your study:
  - A progress report **annually**

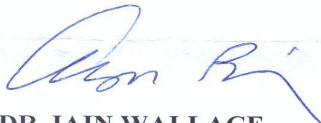
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- Recruitment numbers on a **monthly** basis (if your study should be added to the NIHR research Portfolio you will receive a separate letter from the R&D Office detailing the steps to be taken)
- Report on SAEs and SUSARs if your study is a Clinical Trial of an Investigational Medicinal Product
- Any information required for the purpose of internal or external audit and monitoring
- Copies of any external monitoring reports
- Notification of the end of recruitment and the end of the study
- A copy of the final report, when available.
- Copies of or full citations for any publications or abstracts

The appropriate forms will be provided to you by the Research and Development office when they are needed. Other information may be required from time to time.

Yours sincerely

  
**DR. IAIN WALLACE**  
 Medical Director

CC: NRS Permissions Coordinating Centre (NRS Permissions CC)  
 Research & Development Office  
 Foresterhill House Annexe  
 Foresterhill  
 ABERDEEN  
 AB25 2ZB

Dr Emily Newman  
 Lecturer  
 School of Health in Social Science  
 Teviot Place  
 University of Edinburgh  
 Edinburgh  
 EH8 9AG

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## APPENDIX 6

### Participant Information Sheet

(Parents)



## **Information Sheet**



### **Title of Project: Insulin Pump Use in children with type 1 diabetes: An exploration of families' experiences.**

You are being invited to take part in a research study that is being conducted in part fulfillment of my Doctorate in Clinical Psychology degree at the University of Edinburgh. Before you take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please contact me (Lesley Allan, Trainee Clinical Psychologist), if there is anything that is not clear or if you would like more information.

#### ***What is the purpose of the study?***

The aim of the study is to help me understand the experiences of families who have a child with type 1 diabetes and an insulin pump. It seems that personal experiences of this type of treatment have not been evaluated. In this study I would like to ask about your experiences of having a child who has an insulin pump.

#### ***Why have I been chosen?***

Individuals included in this study will be: Children aged between 8 and 14 who have an insulin pump, and their parent/primary caregiver.

#### ***Do I have to take part?***

No. Your participation in the study will be voluntary and your responses will remain anonymous. If you do decide to take part you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you withdraw, your data will be destroyed. A decision to withdraw at any time will not interfere in any way with your child's treatment or care or your relationship with staff in any way.

#### ***Appendices***

***What will happen to me if I take part? What do I have to do?***

If you do decide to take part, you will need to sign a consent form to make sure that you have understood the information on this form.

You and your child will then have one to one interviews with me. You will be asked about your experiences. The purpose of such questions is to find out more about the experiences of families with a child who has an insulin pump. This interview will depend on how much information you wish to share but is expected to last no more than 60 minutes. The interview will take place in a quiet room at your home. Your child will be interviewed separately by me. Their interview should also last no more than 60 minutes (although it is expected to be shorter). They will be asked about their experiences. Breaks can be provided at any point within the interview should you or your child feel upset or tired.

If you would rather be interviewed outwith your home, I can arrange to conduct the interviews at Forth Valley Community Hospital or Stirling Community Hospital.

I would like to audiotape the interviews for better recall and analysis of the information you provide. Afterwards, I will listen to the tapes of the conversations and write a report of what people have said. If you agree, I might ask to meet with you again for ½ hour to look at the report of what you have said. This is to check that what you have said has been reported accurately. Alternatively if it is more convenient, I could send you a copy of the report and telephone you to discuss if what I have reported is accurate.

***What are the possible advantages/disadvantages of taking part?***

The study is not intended to be of direct benefit to yourself or your child. However people who have taken part in similar studies have found it a positive experience to have a chance to feel listened to. I hope that the information I find will help to better understand the views of families with children who have an insulin pump and contribute to a better service.

***Will my information be kept confidential?***

Yes. All the information that is collected during the course of the study will be kept confidential. However, if information that is disclosed throughout the course of the interview indicates a risk to yourself or others then confidentiality would need to be breached and clinical staff informed.



In the study, your name will be replaced with a participant number, and it will not be possible for you to be identified in any reporting of the data gathered. All audio- recordings and transcripts will be kept in a locked cabinet within the Falkirk Community Hospital property. Once the final report is written, all tapes and transcripts will be destroyed. The information you provide in the interview will not be shared by anyone outside the research team unless it indicates a risk to yourself or others. You will not be identified in any reporting of the data gathered.

***What will happen to the results of the study?***

The results of the study will be submitted to Edinburgh University for review and may be published in a report, scientific journal and/or presented in conferences. Direct quotes from interviews will only be used after being made anonymous and any information that might identify you will be removed.

***Can I find out the results?***

Yes. I will contact participants after the study to find out if you would like feedback about the results .

***Did anyone else check that the study is ok to do?***

Yes. The West of Scotland Research Ethics Committee, which has the responsibility for scrutinising proposals for medical research on humans, has examined this proposal and has raised no objections from the point of view of medical ethics.

***What if there is a problem?***

If you think that you or your child has been harmed in any way by taking part in this study, you have the right to make a complaint and ask for compensation from the University of Edinburgh, who are sponsoring this research. You can get details about this from the research team. Also, as a patient of the NHS, you have the right to make a complaint through the NHS process. To do this you can make a complaint in writing to the NHS Forth Valley Patient Relations and Complaint Service, Falkirk Community Hospital, 01324 678 530. If you think you have been harmed because someone has not done their job properly during the study, you may have grounds for legal action against NHS Forth Valley, but you may have to pay your legal costs.

### ***What to do next?***

If you are willing to take part in this study you can arrange an interview when I call at your arranged time. At the meeting I will ask you to complete the consent form before your interview takes place.

Thank you for taking the time to read and consider the above information.

### ***Contacts for further information***

Should you have any further questions about the study, please contact:

Name of Lead Researcher: Lesley Allan, Trainee Clinical Psychologist

Address: Adult Clinical Psychology, Old Nurses Home, Falkirk Community Hospital, Major's Loan, Falkirk, FK1 5QE

Telephone: 01324 614347

Name of Supervisor:

Address:

Telephone:

## APPENDIX 7

### Participant Information Sheet

(Older Children)



## **Information Sheet**

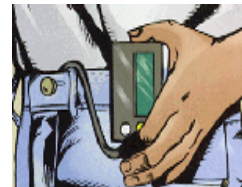
### **Title of Project: Insulin Pump Use in children with type 1 diabetes: An exploration of families' experiences.**

You are being invited to take part in a research study that is being conducted as part of my Doctorate in Clinical Psychology degree at the University of Edinburgh.

Before you take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Please contact the lead researcher (Lesley Allan, Trainee Clinical Psychologist), if there is anything that is not clear or if you would like more information.

#### ***What is the research about?***

The research is about people's experiences of having an insulin pump. We want to hear what that's like for people. We also want to hear what it's like for their family.



#### ***Why have I been chosen?***

You have been chosen because you are aged between 8 and 14 and you have an insulin pump.

#### ***Do I have to take part?***

No, you do not have to take part. If you do decide to take part you can change your mind at any time and you don't need to give a reason. If you withdraw, your data will be destroyed. If you decide to withdraw it won't affect your treatment at the diabetes centre.

#### ***What will happen to me if I take part? What do I have to do?***

If you do decide to take part, you will meet with Lesley at your home. The meeting will be a one

to one interview with Lesley. Lesley will ask you about what it's like to have an insulin pump. This meeting will last less than 60 minutes. Lesley will be happy to give you a break at any point during the interview. Lesley will be meeting with your parent or guardian separately. She will be asking them similar questions to you.

Lesley would like to audiotape the interviews to help her to remember the information you provide.

***Will I be asked difficult or upsetting questions?***

Lesley will ask you about your insulin pump and what it's like for you and your family. Hopefully this won't be upsetting for you.

***Who will hear my tapes?***

All the information that is collected during the course of the study will be kept confidential and locked away. However, if you tell Lesley something that makes her worried about you or someone else, she would have to tell your parent or guardian and your GP.

***Can I find out the results?***

Yes. Lesley will contact you after the study to find out if you want to hear about the results.

***Did anyone else check that the study is ok to do?***

Yes. The West of Scotland Research Ethics Committee, whose job it is to check research studies for medical research on humans, has examined this proposal and has agreed to the research going ahead.

***What if there is a problem?***

If you think that you have been harmed in any way by taking part in this study, you have the right to make a complaint to the University of Edinburgh, who are sponsoring this research or to NHS Forth Valley. You can get details about this from Lesley.

Thank you for taking the time to read this information sheet.



***Contacts for further information***

Should you have any further questions about the study, please contact:



Name of Lead Researcher: Lesley Allan, Trainee Clinical Psychologist

Address: Adult Clinical Psychology, Old Nurses Home, Falkirk Community Hospital, Major's Loan, Falkirk, FK1 5QE

Telephone: 01324 614347

Name of Supervisor:

Address:

Telephone:

## APPENDIX 8

### Participant Information Sheet

(Younger Children)



## **Information Sheet**

### **Title of Project: Insulin Pump Use in children with type 1 diabetes: An exploration of families' experiences.**

You are being asked to take part in a research study that is being carried out as part of my Doctorate in Clinical Psychology degree at the University of Edinburgh.

Before you take part it is important for you to understand why I am doing this and what it will involve.

Please take time to read the following information carefully. Please contact Lesley Allan who is the lead researcher, if there is anything that is not clear or if you would like more information.

#### ***What is the research about?***

The research is about people's experiences of having an insulin pump. We want to hear what that's like for people. We also want to hear what it's like for their family.



#### ***Why have I been chosen?***

You have been chosen because you are aged between 8 and 14 and you have an insulin pump.



#### ***Do I have to take part?***

No, it's up to you whether you take part. If you do decide to take part you can change your mind

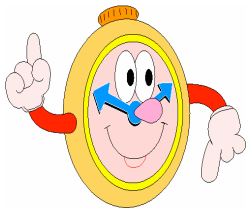


at any time and you don't need to give a reason. If you decide to withdraw it won't affect your treatment at the diabetes centre.

***What will happen to me if I take part? What do I have to do?***

If you do decide to take part, you will meet with Lesley at your home.

The meeting will be an interview with Lesley. Lesley will ask you about what it's like to have an insulin pump.



This meeting will last less than 60 minutes. Lesley will be happy to give you a break at any point during the interview. Lesley will be meeting with your parent or guardian separately. She will be asking them similar questions to you.

Lesley would like to tape record the interviews to help her to remember the information you tell her.

***Will I be asked difficult or upsetting questions?***

Lesley will ask you about your insulin pump and what it's like for you and your family.



Hopefully this won't be upsetting for you.

***Who will hear my tapes?***

All the information that is collected during the course of the study will be kept private and locked away. However, if you tell me something that makes me worried about you or someone else, I would have to tell your parent or guardian and your GP.

***Can I find out the results?***

Yes. Lesley will contact you after the study to find out if you want to hear about the results.



***Did anyone else check that the study is ok to do?***

Yes. The West of Scotland Research Ethics Committee, whose job it is to check over research studies, has examined this proposal and has agreed to the research going ahead.

***What if there is a problem?***

If you think that you have been harmed in any way by taking part in this study, you have the right to make a complaint to the University of Edinburgh, who are sponsoring this research or to NHS Forth Valley. You can get details about this from the research team.



Thank you for taking the time to read this information sheet.

***Contacts for further information***

Should you have any further questions about the study, please contact:



Name of Lead Researcher: Lesley Allan, Trainee Clinical Psychologist

Address: Adult Clinical Psychology, Old Nurses Home, Falkirk Community Hospital, Major's Loan, Falkirk, FK1 5QE

Telephone: 01324 614347

Name of Supervisor:

Address:

Telephone:

## APPENDIX 9

### Consent Sheet



Study No:  
Patient Identification No:

## **Consent Form**



**Title of Project: Insulin Pump Use in children with type 1 diabetes: An exploration of families' experiences.**

**Name of Lead Researcher: Lesley Allan, Trainee Clinical Psychologist**

**Please Initial Box**

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to ask questions and these have been answered.

☐

2. I understand that my participation is voluntary and I have the right to withdraw from the study at any stage without my medical care or rights being affected.

☐

3. I agree to information being audio-taped and transcribed

☐

4. I understand that small parts of my interview may be used for publication in reports. I understand that should this happen, I will not be identified from any of the information provided.

☐

5. I agree to take part in the study.

☐

6. I consent to my son/daughter taking part in this study, and understand that the above conditions apply to him/her also.

☐

\_\_\_\_\_  
Name of Parent/Guardian

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## APPENDIX 10

### Assent Sheet



Study No:  
Patient Identification No:

**Assent Form**



**Title of Project: Insulin Pump Use in children with type 1 diabetes: An exploration of families' experiences.**

**Name of Lead Researcher: Lesley Allan, Trainee Clinical Psychologist**

**Please read the following statements carefully. If you are happy with each statement please tick the box.**

1. I have read and I understand the information sheet for the above study. I have been able to ask questions and these have been answered.

☐

2. I understand that I don't need to take part and I can withdraw from the study at any stage.

☐

3. I agree to my information being audio-taped and listened to.

☐

4. I understand that small parts of my interview may be used for reports. I understand that this happens, my information will be kept private.

☐

5. I agree to take part in the study.

☐

\_\_\_\_\_  
Name of Child

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Researcher

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## APPENDIX 11

### Consent to Contact Sheet



Study No:  
Patient Identification No:

### **Contact Form**



**Title of Project: Insulin Pump Use in children with type 1 diabetes: An exploration of families' experiences.**

**Name of Lead Researcher: Lesley Allan, Trainee Clinical Psychologist**

I agree to Lesley Allan, Trainee Clinical Psychologist contacting me to discuss taking part in the research study.

My contact details are:

Name: \_\_\_\_\_

Relation to child: \_\_\_\_\_

Child's Name: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Telephone Number: \_\_\_\_\_

Ok to leave a message on the answer machine: Yes ☐ No ☐

\_\_\_\_\_  
Name of Parent/Guardian

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Practitioner

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

*Appendices*



## APPENDIX 12

### Interview Schedule

## Topic Guide for interviews (with example questions)

- Diabetes before the insulin pump:
  - What was diabetes like before you got your insulin pump?
  - What was diabetes like for your child before they got their insulin pump?
  - What was it like for you?
- First hearing about the insulin pump:
  - How did you first hear about the insulin pump?
  - Who decided to try the insulin pump?
- Getting started on the insulin pump:
  - Do you remember first getting your insulin pump?
  - What was that like?
  - Do you remember when xx first got the insulin pump?
  - What was that like?
- Learning to first use the insulin pump:
  - Who taught you to use the insulin pump?
  - What was it like learning to use it?
- Managing the insulin pump:
  - What is it like using it now?
  - Who manages the pump?
- The effects of the insulin pump on the child's life:
  - Tell me about the overall effects that the insulin pump has had on your life?
- The effects of the insulin pump on family's lives:
  - Tell me about the overall effects that the insulin pump has had on your family's lives?

## APPENDIX 13

### Example of Coded Transcript

(Family No 2)



Strive for Normality	<p>best as possible [laughs] we could get back to some sort of normal life</p> <p>I: right</p> <p>P2: ...and that's really, the pump for us.</p> <p>I: What, what, what would you mean by normal life?</p> <p>P2: As in sitting down, ok she still has to count her carbs, that's part of life now for us, but she then, now doesn't have to go and inject, she doesn't have, she, she was not too bad at taking injections, em, but it was the quant- the quantity she had to take, em [pause] that she can now know that all she needs to do is sit and still do her carb count but then just press a button. Out for a meal, carb count and press a button, not having to find toilets, not having for us, who is she away with, is she away with a friend, is she away with a friend who knows what happens when she has to inject, all those worries are no longer there.</p>	<p>Normal Life</p> <p><b>Back to Normal</b></p> <p><b>What is normal?</b></p> <p><i>That's part of life for us</i></p> <p><u>Diabetes is part of life</u></p> <p><b>Permanence of diabetes</b></p> <p><i>Quantity</i></p> <p><b>Burden of injections</b></p> <p><i>Just press a button</i></p> <p><b>Simplicity</b></p> <p><b>Not feeling restricted</b></p> <p><b>Pump is better</b></p> <p><i>Not having to...diabetes imposes rules</i></p> <p><u>Pump removes worries</u></p>
Pump is better		
Just Press a Button		
Psychological Enablement		
Flexibility- Practical Enablement		

<p>Uncertainty</p> <p>Powerless</p>	<p>I: okay.</p> <p>P2: ...for the injection point of view, where's she going to inject, who's gonna be with her</p> <p>I: What was it like when she was having to do those injections then?</p> <p>P2: [pause] em [pause] she, shes very mature with regards to her diabetes and everything else health wise that's went on with her so, she accepted that she had to do it [pause] but, it was how often, it was getting worse how often she had to inject, em and that was very, em [long pause] that's what got her down {yeah} That's what got her down the most, having to do as many injections.</p> <p>I: okay</p>	<p><u>Worrying about child</u> <u>Worries about injections</u></p>
<p>Acceptance</p> <p>Psychological Enablement</p> <p>Looking to the future</p>	<p>P2: and that obviously didn't feel normal, having to do that</p>	<p><i>Accepted that</i></p> <p><b>Accepted diabetes?</b></p> <p><b>Diabetes getting worse? Thinking about the future?</b></p> <p><b>Worry about diabetes</b> <b>Worry about the future</b></p> <p><b>Emotional impact of diabetes</b></p>
<p>Strive for Normality</p>		<p><b>Feeling normal</b></p>

Emerging Themes	Child Transcript	Exploratory Comments
	I = Interviewer C2 = Child 2	<u>Underlined = Descriptive</u> <i>Italics = Linguistic</i> <b>Bold = Conceptual</b>
<p>Effort of Diabetes</p> <p>Diabetes is Hard Work</p> <p>Having Choices</p>	<p>What was it like having to, what was it like doing jags? That, that many jags?</p> <p>C2: I got quite annoyed at some points I would like, at one point I think I refused once [pause] cos I just had fed, got fed up with it [pause] em, that was only for, it wasn't even for an hour or so I just [pause] em I just em, but, afterwards it was fine, I just got a bit annoyed</p> <p>I: mm hmm</p>	<p><u>Having already described doing a lot of jags.</u></p> <p><b>Emotional impact</b> <u>Annoyed...sometimes.</u> <b>Is this allowed?</b> <b>Refusing?</b> <b>Choosing?</b> <b>Getting fed up with diabetes</b> Getting <i>annoyed</i> with diabetes and jags <b>Implies it wasn't a regular occurrence</b> <b>Effort of diabetes</b> <i>Annoyed...used twice</i></p>
<p>Routines of Diabetes</p> <p>Hard Work</p>	<p>C2: like sometimes I would get annoyed cos I would have to do my blood sugars for dinner and stuff like that [pause] its fine now [laughs]</p> <p>I: okay and what, what was your diabetes like when you were taking the jags?</p>	<p><i>Annoyed</i></p> <p><u>Routines of diabetes e.g. testing</u></p> <p><i>Fine now</i></p>

<p>Locus of Control</p> <p>Who control's diabetes</p> <p>Who control's the pump</p>	<p>C2: em [pause] it was quite good, em [pause] I got it quite under control but like at some points [pause] em, it would, it was hard, because it, you cant, em [pause] with the pump you can set it for a time limit that you want it go on for and you can switch it off and stuff like that but you couldn't do that with the pen, once it was in it was in, you couldn't [pause] em, it would just go straight in, it wouldn't like last over a (inaudible 05:03), well some insulin would but [pause] em sometimes wouldn't</p> <p>I: so what did that mean then?</p>	<p><u>Describing diabetes before the pump</u>  <i>Diabetes was quite good...</i>  <b>What does quite mean?</b>  <i>But it was hard.</i></p> <p><u>Comparison to the pump</u></p> <p><b>Injections were hard</b>  <b>You can control the pump</b></p> <p><i>Couldn't</i>  <i>Wouldn't</i></p> <p><b>Ability to stop the pump</b>  <b>Permanence of injection</b>  <i>Use of the term 'I'</i></p>
<p>Flexibility of pump</p> <p>Locus of Control</p>	<p>C2: em, like on the pump you can set it, some foods are, take longer [long pause] to [pause] em, go into your system, like I think it was rice and pasta, and you can set it for like a time, distance to go on for [pause] so's that it's not all firing at once cos, it's, especially with, like, chewy sweets like, skittles and stuff like that, that makes you go, really high and then it, makes you dip</p>	<p><u>Describing features of the pump</u>  <u>Understanding the pump</u></p> <p><b>You can set it</b>  <b>Being in control</b>  <b>Taking responsibility for it</b></p> <p><i>Firing</i></p> <p><i>It makes you</i>  <b>Does it control things?</b>  <i>Really high</i></p>



<p>Pump is better</p> <p>Diabetes is permanent</p> <p>Locus of Control</p>	<p>I: right</p> <p>C2: really quite low, so you could set it over for a period of time so that its not giving you it all, its not...</p> <p>I: okay. So [pause] what do you think of that?</p> <p>C2: I think it's really quite good [laughs] cos you couldn't do that with the pen it would just be in and then... the pen also I had to do it my blood sugars quite regular, eh, just incase, but, with the pump it, you don't need as many checks, but you do still need to check but not as many</p> <p>I: why don't you need as many?</p> <p>C2: em, I just find that like your, with more control with the pump [pause] but, I think [pause] with the pen you didn't have as much control, so it meant that your sugars would be [pause] a bit out, sometimes, so you would have to do it, your blood sugars more regular</p>	<p><i>Really quite low</i></p> <p><i>It's not giving you</i></p> <p><b>Does it have control?</b></p> <p><u>Comparison to injections</u></p> <p><u>Pump is better</u></p> <p><u>Routines of diabetes</u></p> <p><i>Still need to but not as much</i></p> <p><b>Diabetes is still around</b></p> <p><b>Pen can't be trusted</b> <b>Pump can be trusted</b></p> <p><b>Control</b></p> <p><b>Being in control</b> <i>A bit out</i> <b>I control the pump</b></p> <p><b>Taking responsibility</b></p> <p><b>Pump enables control</b> <b>Pen disables control</b></p>
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## APPENDIX 14

### Summary Table of Themes